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Table 15.1.1 Summary of Subject Disposition

	Status	Treatment Sequence 1 (N=7) n (%)	Treatment Sequence 2 (N=7) n (%)	Treatment Sequence 3 (N=7) n (%)	Treatment Sequence 4 (N=7) n (%)	Treatment Sequence 5 (N=7) n (%)	Treatment Sequence 6 (N=7) n (%)	Total (N=42) n (%)
Screened subjects								103
Randomized subjects	Yes	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	42 (100.0)
Subject treated	Yes	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	42 (100.0)
Subjects who completed the trial	Yes	7 (100.0)	5 (71.4)	7 (100.0)	6 (85.7)	6 (85.7)	6 (85.7)	37 (88.1)
	No	0	2 (28.6)	0	1 (14.3)	1 (14.3)	1 (14.3)	5 (11.9)
Subjects who terminated treatment earlier	Yes	0	2 (28.6)	0	1 (14.3)	1 (14.3)	1 (14.3)	5 (11.9)
	No	7 (100.0)	5 (71.4)	7 (100.0)	6 (85.7)	6 (85.7)	6 (85.7)	37 (88.1)
Reason for early treatment termination	Adverse Event	0	1 (14.3)	0	1 (14.3)	0	0	2 (4.8)
	Protocol Non-Compliance	0	1 (14.3)	0	0	0	0	1 (2.4)
	Withdrawal By Subject	0	0	0	0	1 (14.3)	1 (14.3)	2 (4.8)

N: The number of subjects dosed with at least one treatment in that treatment sequence, or the number of subjects in the safety population for the total summary; n: The number of subjects in the specific category.
%: calculated using the number of subjects dosed with at least one treatment for each treatment sequence, or the number of subjects in the safety population for the total summary.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.1.1 Summary of Subject Disposition

		Treatment Sequence 1 (N=7)	Treatment Sequence 2 (N=7)	Treatment Sequence 3 (N=7)	Treatment Sequence 4 (N=7)	Treatment Sequence 5 (N=7)	Treatment Sequence 6 (N=7)	Total (N=42)
	Status	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Subjects who terminated the study prematurely	Yes	0	2 (28.6)	0	1 (14.3)	1 (14.3)	1 (14.3)	5 (11.9)
	No	7 (100.0)	5 (71.4)	7 (100.0)	6 (85.7)	6 (85.7)	6 (85.7)	37 (88.1)
Reasons of withdrawal from the study prematurely	Adverse Event	0	1 (14.3)	0	1 (14.3)	0	0	2 (4.8)
	Protocol Non-Compliance	0	1 (14.3)	0	0	0	0	1 (2.4)
	Withdrawal By Subject	0	0	0	0	1 (14.3)	1 (14.3)	2 (4.8)
Safety Analysis Population	Yes	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	42 (100.0)
PK Analysis Population	Yes	7 (100.0)	5 (71.4)	7 (100.0)	6 (85.7)	6 (85.7)	6 (85.7)	37 (88.1)
	No	0	2 (28.6)	0	1 (14.3)	1 (14.3)	1 (14.3)	5 (11.9)

N: The number of subjects dosed with at least one treatment in that treatment sequence, or the number of subjects in the safety population for the total summary; n: The number of subjects in the specific category.
%: calculated using the number of subjects dosed with at least one treatment for each treatment sequence, or the number of subjects in the safety population for the total summary.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.1.2 Demographic Data (Safety Population)

Demographic characteristic	Statistics	Treatment Sequence 1 (N=7)	Treatment Sequence 2 (N=7)	Treatment Sequence 3 (N=7)	Treatment Sequence 4 (N=7)	Treatment Sequence 5 (N=7)	Treatment Sequence 6 (N=7)	Total (N=42) n (%)
Age (yr)	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)
	Mean (SD)	31.1 (7.20)	38.0 (10.66)	38.9 (11.23)	32.6 (9.55)	33.0 (10.17)	35.9 (12.55)	34.9 (10.13)
	Median	27.0	42.0	43.0	34.0	32.0	43.0	35.0
	Min; Max	24; 42	26; 50	19; 50	18; 45	22; 47	21; 48	18; 50
Sex, n (%)	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)
	Male	3 (42.9)	3 (42.9)	3 (42.9)	3 (42.9)	3 (42.9)	4 (57.1)	19 (45.2)
	Female	4 (57.1)	4 (57.1)	4 (57.1)	4 (57.1)	4 (57.1)	3 (42.9)	23 (54.8)
Race, n (%)	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)
	White	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	42 (100.0)
Ethnicity, n (%)	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)
	Not-Hispanic	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	7 (100.0)	42 (100.0)

Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with at least one treatment in that treatment sequence, or the number subjects in the safety population for the total summary; n: The number of subjects in the specific category; %: calculated using the number of subjects dosed with at least one treatment for each treatment sequence, or the number of subjects in the safety population for the total summary; SD: Standard deviation.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.1.2 Demographic Data (Safety Population)

Demographic characteristic	Statistics	Treatment Sequence 1 (N=7)	Treatment Sequence 2 (N=7)	Treatment Sequence 3 (N=7)	Treatment Sequence 4 (N=7)	Treatment Sequence 5 (N=7)	Treatment Sequence 6 (N=7)	Total (N=42) n (%)
Height (cm)	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)
	Mean (SD)	172.0 (6.03)	170.9 (7.93)	176.9 (10.16)	174.1 (9.69)	171.9 (5.24)	174.1 (7.17)	173.3 (7.68)
	Median	171.0	168.0	173.0	176.0	171.0	174.0	171.5
	Min; Max	165; 180	162; 184	165; 189	160; 185	166; 182	163; 183	160; 189
Weight (kg)	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)
	Mean (SD)	70.23 (9.790)	69.79 (7.523)	71.27 (11.686)	66.06 (8.760)	65.37 (7.780)	71.94 (11.383)	69.11 (9.369)
	Median	74.50	66.40	69.00	68.50	65.10	69.00	67.75
	Min; Max	56.2; 81.0	59.7; 79.0	53.0; 90.0	51.0; 76.7	54.0; 78.6	55.0; 87.3	51.0; 90.0
BMI (kg/m^2)	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)
	Mean (SD)	23.67 (2.469)	23.90 (2.026)	22.67 (1.884)	21.69 (1.068)	22.10 (1.865)	23.64 (2.700)	22.95 (2.119)
	Median	23.60	24.50	23.00	22.10	22.80	23.70	22.85
	Min; Max	20.6; 28.0	19.9; 26.5	19.5; 25.5	19.9; 22.9	19.3; 23.8	19.0; 26.8	19.0; 28.0

Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with at least one treatment in that treatment sequence, or the number subjects in the safety population for the total summary; n: The number of subjects in the specific category; %: calculated using the number of subjects dosed with at least one treatment for each treatment sequence, or the number of subjects in the safety population for the total summary; SD: Standard deviation.

Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.

Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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15.2 Efficacy Data

There were no efficacy assessments performed during the trial.

15.3 Safety Data

15.3.1 Display of Adverse Events

Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Intensity (Safety Population)

Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Intensity (Safety Population)

Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Causality (Safety Population)

Table 15.3.1.4 Summary of Treatment-Emergent Adverse Events Leading to Withdrawal, by System Organ Class and Preferred Term (Safety Population)

Levothyroxine
EMR 200125-002

Dosage Form Proportionality of Levothyroxine New Formulations (50 µg, 100 µg, and 200 µg Tablets) in Fasted State

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Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

	Treatment A (N=38)		Treatment B (N=40)		Treatment C (N=39)		Total (N=42)	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	11 (28.9)	27	16 (40.0)	27	13 (33.3)	31	27 (64.3)	85
Cardiac Disorders	2 (5.3)	2	0	0	1 (2.6)	1	2 (4.8)	3
Palpitations	2 (5.3)	2	0	0	1 (2.6)	1	2 (4.8)	3
Eye Disorders	0	0	1 (2.5)	1	0	0	1 (2.4)	1
Diplopia	0	0	1 (2.5)	1	0	0	1 (2.4)	1
Gastrointestinal Disorders	3 (7.9)	7	2 (5.0)	4	6 (15.4)	10	11 (26.2)	21
Abdominal Discomfort	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Abdominal Pain	1 (2.6)	1	0	0	0	0	1 (2.4)	1
Abdominal Pain Lower	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Diarrhoea	2 (5.3)	2	1 (2.5)	1	0	0	3 (7.1)	3
Nausea	2 (5.3)	2	1 (2.5)	1	5 (12.8)	7	8 (19.0)	10
Vomiting	2 (5.3)	2	2 (5.0)	2	1 (2.6)	1	5 (11.9)	5
General Disorders And Administration Site Conditions	3 (7.9)	4	2 (5.0)	3	1 (2.6)	1	6 (14.3)	8
Asthenia	1 (2.6)	1	1 (2.5)	1	0	0	2 (4.8)	2
Catheter Site Phlebitis	0	0	1 (2.5)	1	0	0	1 (2.4)	1
Fatigue	1 (2.6)	1	1 (2.5)	1	0	0	2 (4.8)	2

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Treatment A (N=38) Subjects n (%)	 Events n	Treatment B (N=40) Subjects n (%)	 Events n	Treatment C (N=39) Subjects n (%)	 Events n	Total (N=42) Subjects n (%)	 Events n
Hunger	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Non-Cardiac Chest Pain	1 (2.6)	1	0	0	0	0	1 (2.4)	1
Pyrexia	1 (2.6)	1	0	0	0	0	1 (2.4)	1
Infections And Infestations	3 (7.9)	4	4 (10.0)	4	1 (2.6)	1	7 (16.7)	9
Nasopharyngitis	2 (5.3)	3	4 (10.0)	4	1 (2.6)	1	6 (14.3)	8
Otitis Media	1 (2.6)	1	0	0	0	0	1 (2.4)	1
Injury, Poisoning And Procedural Complications	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Muscle Rupture	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Musculoskeletal And Connective Tissue Disorders	2 (5.3)	2	1 (2.5)	1	0	0	3 (7.1)	3
Back Pain	1 (2.6)	1	1 (2.5)	1	0	0	2 (4.8)	2
Pain In Extremity	1 (2.6)	1	0	0	0	0	1 (2.4)	1
Nervous System Disorders	5 (13.2)	6	8 (20.0)	12	6 (15.4)	13	14 (33.3)	31
Dizziness	4 (10.5)	4	1 (2.5)	1	2 (5.1)	4	5 (11.9)	9
Headache	2 (5.3)	2	8 (20.0)	11	5 (12.8)	9	12 (28.6)	22

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.1 Summary of Treatment-Emergent Adverse Events by System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Treatment A (N=38) Subjects n (%)	Treatment A (N=38) Events n	Treatment B (N=40) Subjects n (%)	Treatment B (N=40) Events n	Treatment C (N=39) Subjects n (%)	Treatment C (N=39) Events n	Total (N=42) Subjects n (%)	Total (N=42) Events n
Psychiatric Disorders	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Sleep Disorder	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Respiratory, Thoracic And Mediastinal Disorders	1 (2.6)	1	1 (2.5)	1	1 (2.6)	1	3 (7.1)	3
Nasal Congestion	0	0	0	0	1 (2.6)	1	1 (2.4)	1
Oropharyngeal Pain	1 (2.6)	1	1 (2.5)	1	0	0	2 (4.8)	2
Skin And Subcutaneous Tissue Disorders	0	0	1 (2.5)	1	0	0	1 (2.4)	1
Dermatitis Atopic	0	0	1 (2.5)	1	0	0	1 (2.4)	1
Vascular Disorders	1 (2.6)	1	0	0	2 (5.1)	2	3 (7.1)	3
Deep Vein Thrombosis	1 (2.6)	1	0	0	0	0	1 (2.4)	1
Hot Flush	0	0	0	0	2 (5.1)	2	2 (4.8)	2

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment A Subjects (N=38) Events (n=27)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	10 (26.3)	16	7 (18.4)	11	0	0
Cardiac Disorders	2 (5.3)	2	0	0	0	0
Palpitations	2 (5.3)	2	0	0	0	0
Eye Disorders	0	0	0	0	0	0
Diplopia	0	0	0	0	0	0
Gastrointestinal Disorders	2 (5.3)	3	2 (5.3)	4	0	0
Abdominal Discomfort	0	0	0	0	0	0
Abdominal Pain	0	0	1 (2.6)	1	0	0
Abdominal Pain Lower	0	0	0	0	0	0
Diarrhoea	1 (2.6)	1	1 (2.6)	1	0	0
Nausea	1 (2.6)	1	1 (2.6)	1	0	0
Vomiting	1 (2.6)	1	1 (2.6)	1	0	0
General Disorders And Administration Site Conditions	3 (7.9)	3	1 (2.6)	1	0	0
Asthenia	0	0	1 (2.6)	1	0	0
Catheter Site Phlebitis	0	0	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

System Organ Class Preferred Term	Treatment A Subjects (N=38) Events (n=27) Mild Subjects n (%)	Events n	Moderate Subjects n (%)	Events n	Severe Subjects n (%)	Events n
Fatigue	1 (2.6)	1	0	0	0	0
Hunger	0	0	0	0	0	0
Non-Cardiac Chest Pain	1 (2.6)	1	0	0	0	0
Pyrexia	1 (2.6)	1	0	0	0	0
Infections And Infestations	2 (5.3)	2	2 (5.3)	2	0	0
Nasopharyngitis	2 (5.3)	2	1 (2.6)	1	0	0
Otitis Media	0	0	1 (2.6)	1	0	0
Injury, Poisoning And Procedural Complications	0	0	0	0	0	0
Muscle Rupture	0	0	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	0	0	2 (5.3)	2	0	0
Back Pain	0	0	1 (2.6)	1	0	0
Pain In Extremity	0	0	1 (2.6)	1	0	0
Nervous System Disorders	4 (10.5)	5	1 (2.6)	1	0	0
Dizziness	3 (7.9)	3	1 (2.6)	1	0	0
Headache	2 (5.3)	2	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment A Subjects (N=38) Events (n=27)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Psychiatric Disorders	0	0	0	0	0	0
Sleep Disorder	0	0	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	1 (2.6)	1	0	0	0	0
Nasal Congestion	0	0	0	0	0	0
Oropharyngeal Pain	1 (2.6)	1	0	0	0	0
Skin And Subcutaneous Tissue Disorders	0	0	0	0	0	0
Dermatitis Atopic	0	0	0	0	0	0
Vascular Disorders	0	0	1 (2.6)	1	0	0
Deep Vein Thrombosis	0	0	1 (2.6)	1	0	0
Hot Flush	0	0	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment B Subjects (N=40) Events (n=27)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	16 (40.0)	22	3 (7.5)	4	1 (2.5)	1
Cardiac Disorders	0	0	0	0	0	0
Palpitations	0	0	0	0	0	0
Eye Disorders	1 (2.5)	1	0	0	0	0
Diplopia	1 (2.5)	1	0	0	0	0
Gastrointestinal Disorders	2 (5.0)	2	1 (2.5)	1	1 (2.5)	1
Abdominal Discomfort	0	0	0	0	0	0
Abdominal Pain	0	0	0	0	0	0
Abdominal Pain Lower	0	0	0	0	0	0
Diarrhoea	1 (2.5)	1	0	0	0	0
Nausea	0	0	1 (2.5)	1	0	0
Vomiting	1 (2.5)	1	0	0	1 (2.5)	1
General Disorders And Administration Site Conditions	2 (5.0)	3	0	0	0	0
Asthenia	1 (2.5)	1	0	0	0	0
Catheter Site Phlebitis	1 (2.5)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment B Subjects (N=40) Events (n=27)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Fatigue	1 (2.5)	1	0	0	0	0
Hunger	0	0	0	0	0	0
Non-Cardiac Chest Pain	0	0	0	0	0	0
Pyrexia	0	0	0	0	0	0
Infections And Infestations	3 (7.5)	3	1 (2.5)	1	0	0
Nasopharyngitis	3 (7.5)	3	1 (2.5)	1	0	0
Otitis Media	0	0	0	0	0	0
Injury, Poisoning And Procedural Complications	0	0	0	0	0	0
Muscle Rupture	0	0	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	1 (2.5)	1	0	0	0	0
Back Pain	1 (2.5)	1	0	0	0	0
Pain In Extremity	0	0	0	0	0	0
Nervous System Disorders	7 (17.5)	10	2 (5.0)	2	0	0
Dizziness	1 (2.5)	1	0	0	0	0
Headache	7 (17.5)	9	2 (5.0)	2	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

/project24/ep/blinded/e210898_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.2.sas

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment B Subjects (N=40) Events (n=27)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Psychiatric Disorders	0	0	0	0	0	0
Sleep Disorder	0	0	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	1 (2.5)	1	0	0	0	0
Nasal Congestion	0	0	0	0	0	0
Oropharyngeal Pain	1 (2.5)	1	0	0	0	0
Skin And Subcutaneous Tissue Disorders	1 (2.5)	1	0	0	0	0
Dermatitis Atopic	1 (2.5)	1	0	0	0	0
Vascular Disorders	0	0	0	0	0	0
Deep Vein Thrombosis	0	0	0	0	0	0
Hot Flush	0	0	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment C Subjects (N=39) Events (n=31)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	12 (30.8)	21	6 (15.4)	10	0	0
Cardiac Disorders	1 (2.6)	1	0	0	0	0
Palpitations	1 (2.6)	1	0	0	0	0
Eye Disorders	0	0	0	0	0	0
Diplopia	0	0	0	0	0	0
Gastrointestinal Disorders	4 (10.3)	7	3 (7.7)	3	0	0
Abdominal Discomfort	1 (2.6)	1	0	0	0	0
Abdominal Pain	0	0	0	0	0	0
Abdominal Pain Lower	0	0	1 (2.6)	1	0	0
Diarrhoea	0	0	0	0	0	0
Nausea	4 (10.3)	5	2 (5.1)	2	0	0
Vomiting	1 (2.6)	1	0	0	0	0
General Disorders And Administration Site Conditions	1 (2.6)	1	0	0	0	0
Asthenia	0	0	0	0	0	0
Catheter Site Phlebitis	0	0	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment C Subjects (N=39) Events (n=31)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Fatigue	0	0	0	0	0	0
Hunger	1 (2.6)	1	0	0	0	0
Non-Cardiac Chest Pain	0	0	0	0	0	0
Pyrexia	0	0	0	0	0	0
Infections And Infestations	1 (2.6)	1	0	0	0	0
Nasopharyngitis	1 (2.6)	1	0	0	0	0
Otitis Media	0	0	0	0	0	0
Injury, Poisoning And Procedural Complications	1 (2.6)	1	0	0	0	0
Muscle Rupture	1 (2.6)	1	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	0	0	0	0	0	0
Back Pain	0	0	0	0	0	0
Pain In Extremity	0	0	0	0	0	0
Nervous System Disorders	5 (12.8)	7	3 (7.7)	6	0	0
Dizziness	2 (5.1)	2	1 (2.6)	2	0	0
Headache	4 (10.3)	5	2 (5.1)	4	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Treatment C Subjects (N=39) Events (n=31)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Psychiatric Disorders	1 (2.6)	1	0	0	0	0
Sleep Disorder	1 (2.6)	1	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	0	0	1 (2.6)	1	0	0
Nasal Congestion	0	0	1 (2.6)	1	0	0
Oropharyngeal Pain	0	0	0	0	0	0
Skin And Subcutaneous Tissue Disorders	0	0	0	0	0	0
Dermatitis Atopic	0	0	0	0	0	0
Vascular Disorders	2 (5.1)	2	0	0	0	0
Deep Vein Thrombosis	0	0	0	0	0	0
Hot Flush	2 (5.1)	2	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Total Subjects (N=42) Events (n=85)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	27 (64.3)	59	15 (35.7)	25	1 (2.4)	1
Cardiac Disorders	2 (4.8)	3	0	0	0	0
Palpitations	2 (4.8)	3	0	0	0	0
Eye Disorders	1 (2.4)	1	0	0	0	0
Diplopia	1 (2.4)	1	0	0	0	0
Gastrointestinal Disorders	8 (19.0)	12	6 (14.3)	8	1 (2.4)	1
Abdominal Discomfort	1 (2.4)	1	0	0	0	0
Abdominal Pain	0	0	1 (2.4)	1	0	0
Abdominal Pain Lower	0	0	1 (2.4)	1	0	0
Diarrhoea	2 (4.8)	2	1 (2.4)	1	0	0
Nausea	5 (11.9)	6	4 (9.5)	4	0	0
Vomiting	3 (7.1)	3	1 (2.4)	1	1 (2.4)	1
General Disorders And Administration Site Conditions	6 (14.3)	7	1 (2.4)	1	0	0
Asthenia	1 (2.4)	1	1 (2.4)	1	0	0
Catheter Site Phlebitis	1 (2.4)	1	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

	Total Subjects (N=42) Events (n=85)					
	Mild		Moderate		Severe	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Fatigue	2 (4.8)	2	0	0	0	0
Hunger	1 (2.4)	1	0	0	0	0
Non-Cardiac Chest Pain	1 (2.4)	1	0	0	0	0
Pyrexia	1 (2.4)	1	0	0	0	0
Infections And Infestations	5 (11.9)	6	3 (7.1)	3	0	0
Nasopharyngitis	5 (11.9)	6	2 (4.8)	2	0	0
Otitis Media	0	0	1 (2.4)	1	0	0
Injury, Poisoning And Procedural Complications	1 (2.4)	1	0	0	0	0
Muscle Rupture	1 (2.4)	1	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	1 (2.4)	1	2 (4.8)	2	0	0
Back Pain	1 (2.4)	1	1 (2.4)	1	0	0
Pain In Extremity	0	0	1 (2.4)	1	0	0
Nervous System Disorders	12 (28.6)	22	6 (14.3)	9	0	0
Dizziness	4 (9.5)	6	2 (4.8)	3	0	0
Headache	11 (26.2)	16	4 (9.5)	6	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.2 Summary of Treatment-Emergent Adverse Events by Intensity (Safety Population)

System Organ Class Preferred Term	Total Subjects (N=42) Events (n=85)					
	Mild		Moderate		Severe	
	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Psychiatric Disorders	1 (2.4)	1	0	0	0	0
Sleep Disorder	1 (2.4)	1	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	2 (4.8)	2	1 (2.4)	1	0	0
Nasal Congestion	0	0	1 (2.4)	1	0	0
Oropharyngeal Pain	2 (4.8)	2	0	0	0	0
Skin And Subcutaneous Tissue Disorders	1 (2.4)	1	0	0	0	0
Dermatitis Atopic	1 (2.4)	1	0	0	0	0
Vascular Disorders	2 (4.8)	2	1 (2.4)	1	0	0
Deep Vein Thrombosis	0	0	1 (2.4)	1	0	0
Hot Flush	2 (4.8)	2	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Treatment A Subjects (N=38) Events (n=27)				Treatment B Subjects (N=40) Events (n=27)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	5 (13.2)	9	9 (23.7)	18	6 (15.0)	10	11 (27.5)	17
Cardiac Disorders	0	0	2 (5.3)	2	0	0	0	0
Palpitations	0	0	2 (5.3)	2	0	0	0	0
Eye Disorders	0	0	0	0	1 (2.5)	1	0	0
Diplopia	0	0	0	0	1 (2.5)	1	0	0
Gastrointestinal Disorders	2 (5.3)	5	1 (2.6)	2	1 (2.5)	1	1 (2.5)	3
Abdominal Discomfort	0	0	0	0	0	0	0	0
Abdominal Pain	1 (2.6)	1	0	0	0	0	0	0
Abdominal Pain Lower	0	0	0	0	0	0	0	0
Diarrhoea	2 (5.3)	2	0	0	0	0	1 (2.5)	1
Nausea	1 (2.6)	1	1 (2.6)	1	0	0	1 (2.5)	1
Vomiting	1 (2.6)	1	1 (2.6)	1	1 (2.5)	1	1 (2.5)	1
General Disorders And Administration Site Conditions	1 (2.6)	1	2 (5.3)	3	1 (2.5)	2	1 (2.5)	1
Asthenia	0	0	1 (2.6)	1	1 (2.5)	1	0	0
Catheter Site Phlebitis	0	0	0	0	0	0	1 (2.5)	1

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).

Treatment A: 12 tablets of 50 µg of levothyroxine;Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Treatment A Subjects (N=38) Events (n=27)				Treatment B Subjects (N=40) Events (n=27)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Fatigue	1 (2.6)	1	0	0	1 (2.5)	1	0	0
Hunger	0	0	0	0	0	0	0	0
Non-Cardiac Chest Pain	0	0	1 (2.6)	1	0	0	0	0
Pyrexia	0	0	1 (2.6)	1	0	0	0	0
Infections And Infestations	0	0	3 (7.9)	4	0	0	4 (10.0)	4
Nasopharyngitis	0	0	2 (5.3)	3	0	0	4 (10.0)	4
Otitis Media	0	0	1 (2.6)	1	0	0	0	0
Injury, Poisoning And Procedural Complications	0	0	0	0	0	0	0	0
Muscle Rupture	0	0	0	0	0	0	0	0
Musculoskeletal And Connective Tissue Disorders	0	0	2 (5.3)	2	0	0	1 (2.5)	1
Back Pain	0	0	1 (2.6)	1	0	0	1 (2.5)	1
Pain In Extremity	0	0	1 (2.6)	1	0	0	0	0
Nervous System Disorders	2 (5.3)	3	3 (7.9)	3	4 (10.0)	6	4 (10.0)	6
Dizziness	2 (5.3)	2	2 (5.3)	2	1 (2.5)	1	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine;Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.
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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Treatment A Subjects (N=38) Events (n=27)				Treatment B Subjects (N=40) Events (n=27)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Headache	1 (2.6)	1	1 (2.6)	1	4 (10.0)	5	4 (10.0)	6
Psychiatric Disorders	0	0	0	0	0	0	0	0
Sleep Disorder	0	0	0	0	0	0	0	0
Respiratory, Thoracic And Mediastinal Disorders	0	0	1 (2.6)	1	0	0	1 (2.5)	1
Nasal Congestion	0	0	0	0	0	0	0	0
Oropharyngeal Pain	0	0	1 (2.6)	1	0	0	1 (2.5)	1
Skin And Subcutaneous Tissue Disorders	0	0	0	0	0	0	1 (2.5)	1
Dermatitis Atopic	0	0	0	0	0	0	1 (2.5)	1
Vascular Disorders	0	0	1 (2.6)	1	0	0	0	0
Deep Vein Thrombosis	0	0	1 (2.6)	1	0	0	0	0
Hot Flush	0	0	0	0	0	0	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine;Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.
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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Treatment C Subjects (N=39) Events (n=31)				Total Subjects (N=42) Events (n=85)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Subjects with events and total events	7 (17.9)	13	8 (20.5)	18	16 (38.1)	32	21 (50.0)	53
Cardiac Disorders	1 (2.6)	1	0	0	1 (2.4)	1	2 (4.8)	2
Palpitations	1 (2.6)	1	0	0	1 (2.4)	1	2 (4.8)	2
Eye Disorders	0	0	0	0	1 (2.4)	1	0	0
Diplopia	0	0	0	0	1 (2.4)	1	0	0
Gastrointestinal Disorders	4 (10.3)	4	3 (7.7)	6	7 (16.7)	10	5 (11.9)	11
Abdominal Discomfort	0	0	1 (2.6)	1	0	0	1 (2.4)	1
Abdominal Pain	0	0	0	0	1 (2.4)	1	0	0
Abdominal Pain Lower	1 (2.6)	1	0	0	1 (2.4)	1	0	0
Diarrhoea	0	0	0	0	2 (4.8)	2	1 (2.4)	1
Nausea	3 (7.7)	3	2 (5.1)	4	4 (9.5)	4	4 (9.5)	6
Vomiting	0	0	1 (2.6)	1	2 (4.8)	2	3 (7.1)	3
General Disorders And Administration Site Conditions	0	0	1 (2.6)	1	2 (4.8)	3	4 (9.5)	5
Asthenia	0	0	0	0	1 (2.4)	1	1 (2.4)	1
Catheter Site Phlebitis	0	0	0	0	0	0	1 (2.4)	1

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Treatment C Subjects (N=39) Events (n=31)				Total Subjects (N=42) Events (n=85)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Fatigue	0	0	0	0	2 (4.8)	2	0	0
Hunger	0	0	1 (2.6)	1	0	0	1 (2.4)	1
Non-Cardiac Chest Pain	0	0	0	0	0	0	1 (2.4)	1
Pyrexia	0	0	0	0	0	0	1 (2.4)	1
Infections And Infestations	0	0	1 (2.6)	1	0	0	7 (16.7)	9
Nasopharyngitis	0	0	1 (2.6)	1	0	0	6 (14.3)	8
Otitis Media	0	0	0	0	0	0	1 (2.4)	1
Injury, Poisoning And Procedural Complications	0	0	1 (2.6)	1	0	0	1 (2.4)	1
Muscle Rupture	0	0	1 (2.6)	1	0	0	1 (2.4)	1
Musculoskeletal And Connective Tissue Disorders	0	0	0	0	0	0	3 (7.1)	3
Back Pain	0	0	0	0	0	0	2 (4.8)	2
Pain In Extremity	0	0	0	0	0	0	1 (2.4)	1
Nervous System Disorders	2 (5.1)	5	4 (10.3)	8	7 (16.7)	14	9 (21.4)	17
Dizziness	2 (5.1)	4	0	0	4 (9.5)	7	2 (4.8)	2

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).

Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

/project24/ep/blinded/e210898_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.3 Summary of Treatment-Emergent Adverse Events by Causality to Study Drug (Safety Population)

	Treatment C Subjects (N=39) Events (n=31)				Total Subjects (N=42) Events (n=85)			
	Related		Not Related		Related		Not Related	
System Organ Class Preferred Term	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n	Subjects n (%)	Events n
Headache	1 (2.6)	1	4 (10.3)	8	6 (14.3)	7	7 (16.7)	15
Psychiatric Disorders	1 (2.6)	1	0	0	1 (2.4)	1	0	0
Sleep Disorder	1 (2.6)	1	0	0	1 (2.4)	1	0	0
Respiratory, Thoracic And Mediastinal Disorders	0	0	1 (2.6)	1	0	0	3 (7.1)	3
Nasal Congestion	0	0	1 (2.6)	1	0	0	1 (2.4)	1
Oropharyngeal Pain	0	0	0	0	0	0	2 (4.8)	2
Skin And Subcutaneous Tissue Disorders	0	0	0	0	0	0	1 (2.4)	1
Dermatitis Atopic	0	0	0	0	0	0	1 (2.4)	1
Vascular Disorders	2 (5.1)	2	0	0	2 (4.8)	2	1 (2.4)	1
Deep Vein Thrombosis	0	0	0	0	0	0	1 (2.4)	1
Hot Flush	2 (5.1)	2	0	0	2 (4.8)	2	0	0

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.
/project24/ep/blinded/e210898_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.3.sas

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Table 15.3.1.4 Summary of Treatment-Emergent Adverse Events Leading to Discontinuation (Safety Population)

System Organ Class Preferred Term	Treatment A (N=38) Subjects n (%)	 Events n	Treatment B (N=40) Subjects n (%)	 Events n	Treatment C (N=39) Subjects n (%)	 Events n	Total (N=42) Subjects n (%)	 Events n
Subjects with events and total events	1 (2.6)	1	1 (2.5)	1	0	0	2 (4.8)	2
Gastrointestinal Disorders	0	0	1 (2.5)	1	0	0	1 (2.4)	1
Vomiting	0	0	1 (2.5)	1	0	0	1 (2.4)	1
Vascular Disorders	1 (2.6)	1	0	0	0	0	1 (2.4)	1
Deep Vein Thrombosis	1 (2.6)	1	0	0	0	0	1 (2.4)	1

N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects with specific adverse event; %: calculated using the number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary as the denominator (n/N*100).
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine; Treatment C: 3 tablets of 200 µg of levothyroxine.

/project24/ep/blinded/e210898_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.1.4.sas

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15.3.2 Listing of Deaths, Other Serious and Significant Adverse Events

Table 15.3.2.1 Serious Adverse Events with Outcome Death (Safety Population)

Table 15.3.2.2 Serious Adverse Events (Safety Population)

Table 15.3.2.3 Serious Adverse Events Leading to Study Discontinuation (Safety Population)

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Table 15.3.2.1 Serious Adverse Events with Outcome of Death (Safety Population)

Subject Number/ Random Number	System Org.Class/ Preferred Term/ Reported Term	Serious Criteria	Onset Date /Time	Resolution Date/ Time(AE Duration hh:mm)	Severity	Relatio--nship	Action Taken with Study Treatment	Other Action Taken	Outcome	Treatment at Onset

There was no serious adverse event with outcome of death in this trial.

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Table 15.3.2.2 Serious Adverse Events (Safety Population)

Subject Number/ Random Number	System Org.Class/ Preferred Term/ Reported Term	Serious Criteria	Onset Date /Time	Resolution Date/ Time(AE Duration hh:mm)	Severity	Relatio--nship	Action Taken with Study Treatment	Other Action Taken	Outcome	Treatment at Onset
	Vascular Disorders / Deep Vein Thrombosis / Deep Vein Thrombosis Left Thigh	Yes	2013-12-17 /22:00		Moderate	Not Related	Drug Withdrawn	Multiple	Not Recovered/Not Resolved	Treatment A

MedDRA: Medical Dictionary for Regulatory Activities; AE duration = AE Resolution date/time - Onset Date/time.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine.

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Table 15.3.2.3 Serious Adverse Events Leading to Study Discontinuation (Safety Population)

Subject Number/ Random Number	System Org.Class/ Preferred Term/ Reported Term	Serious Criteria	Onset Date /Time	Resolution Date/ Time(AE Duration hh:mm)	Severity	Relatio-nship	Action Taken with Study Treatment	Other Action Taken	Outcome	Treatment at Onset
	Vascular Disorders / Deep Vein Thrombosis / Deep Vein Thrombosis Left Thigh	Yes	2013-12-17 /22:00		Moderate	Not Related	Drug Withdrawn	Multiple	Not Recovered/Not Resolved	Treatment A

MedDRA: Medical Dictionary for Regulatory Activities; AE duration = AE Resolution date/time - Onset Date/time.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine;
Treatment C: 3 tablets of 200 µg of levothyroxine.

/project24/ep/blinded/e210898_merc/stats/versioncontrol/primary/scripts/program/main/TFL programs/Tables/Table 15.3.2.3.sas

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15.3.3 Narratives of Deaths, Serious Adverse Events and Significant Adverse Events

No subject died during the trial. Two (2) subjects were withdrawn from the trail (Subject narratives are provided in Section 12.3.2).

15.3.4 Abnormal Laboratory Value Listing (Each Subject)

Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Glucose (mmol/L)	Screening	20-11-2013/ 9:59	4.09 (L, ncs)		4.10 - 5.90
	Treatment Sequence 1	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:15	98.7 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:15	4.04 (L, ncs)		4.10 - 5.90
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 8:15	133.2 (L, ncs)		136.0 - 146.0
	Treatment Sequence 1	Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:15	399 (H, ncs)		173 - 369
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:15	54.4 (L, ncs)		62.7 - 150.8
	Treatment Sequence 1	Platelets (10^9/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 7:54	401 (H, ncs)		173 - 369
		Sodium (mmol/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 7:54	135.0 (L, ncs)		136.0 - 146.0
	Treatment Sequence 1	Erythrocytes (/HPF)	Follow-Up	25-02-2014/ 9:06	30.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Follow-Up	25-02-2014/ 9:06	150.00 (H, ncs)	150	0.00 - 5.00
	Treatment Sequence 1	Amylase (IU/L)	Follow-Up	25-02-2014/ 9:07	101.5 (H, ncs)	33.4	28.0 - 100.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Bilirubin (umol/L)	Follow-Up	25-02-2014/ 9:07	3.8 (L, ncs)	-4.9	5.0 - 21.0
		Hemoglobin (g/L)	Follow-Up	25-02-2014/ 9:07	110 (L, ncs)	-10	111 - 146
		Neutrophils/Leukocytes (%)	Follow-Up	25-02-2014/ 9:07	71.9 (H, ncs)	12.6	37.9 - 70.5
		Platelets (10^9/L)	Follow-Up	25-02-2014/ 9:07	382 (H, ncs)	28	173 - 369
		Thyroxine (nmol/L)	Follow-Up	25-02-2014/ 9:07	55.5 (L, ncs)	-14.1	62.7 - 150.8
	Treatment Sequence 6	Hemoglobin (g/L)	Screening	20-11-2013/11:15	109 (L, ncs)		111 - 146
	Treatment Sequence 6	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:00	25.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 6	Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:11	134.4 (L, ncs)		136.0 - 146.0
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:11	5.19 (H, ncs)		4.02 - 5.08
	Treatment Sequence 6	Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 9:00	135.1 (L, ncs)		136.0 - 146.0
	Treatment Sequence 6	Erythrocytes (10^12/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:48	5.19 (H, ncs)		4.02 - 5.08

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 6	Hemoglobin (g/L)	Follow-Up	05-03-2014/ 7:36	108 (L, ncs)	-1	111 - 146
		Calcium (mmol/L)	Follow-Up	05-03-2014/ 7:36	2.19 (L, ncs)	-0.11	2.20 - 2.65
	Treatment Sequence 1	Calcium (mmol/L)	Screening	21-11-2013/ 8:48	2.19 (L, ncs)		2.20 - 2.65
		Creatinine (umol/L)	Screening	21-11-2013/ 8:48	44.1 (L, ncs)		45.0 - 84.0
		Protein (mL/min/1.73m2)	Screening	21-11-2013/ 8:48	65.8 (L, ncs)		66.0 - 83.0
	Treatment Sequence 1	Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:14	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 1	Calcium (mmol/L)	Follow-Up	06-03-2014/ 8:39	2.17 (L, ncs)	-0.02	2.20 - 2.65
		Creatinine (umol/L)	Follow-Up	06-03-2014/ 8:39	44.1 (L, ncs)	0	45.0 - 84.0
		Protein (mL/min/1.73m2)	Follow-Up	06-03-2014/ 8:39	65.9 (L, ncs)	0.1	66.0 - 83.0
	Treatment Sequence 5	Bilirubin (umol/L)	Screening	22-11-2013/12 :06	30.7 (H, ncs)		5.0 - 21.0
		Neutrophils/Leukocytes (%)	Screening	22-11-2013/12 :06	77.2 (H, ncs)		37.9 - 70.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Platelets (10^9/L)	Screening	22-11-2013/12:06	383 (H, ncs)		173 - 369
		Direct Bilirubin (umol/L)	Screening	22-11-2013/12:06	5.3 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	22-11-2013/12:06	25.4 (H, ncs)		1.6 - 17.6
		Leukocytes (10^9/L)	Screening	22-11-2013/12:06	10.82 (H, ncs)		3.69 - 10.04
		Lymphocytes/Leukocytes (%)	Screening	22-11-2013/12:06	14.1 (L, ncs)		17.8 - 48.5
		Neutrophils (10^9/L)	Screening	22-11-2013/12:06	8.35 (H, ncs)		1.61 - 6.45
	Treatment Sequence 5	Bilirubin (umol/L)	Screening	29-11-2013/9:06	21.7 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	29-11-2013/9:06	4.1 (H, ncs)		0.0 - 3.4
	Treatment Sequence 5	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	03-12-2013/8:17	25.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 5	Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/8:20	373 (H, ncs)		173 - 369
		Protein (mL/min/1.73m2)	Period 1,Day -1/ 24 H Predose	03-12-2013/8:20	62.6 (L, ncs)		66.0 - 83.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:20	0.51 (H, ncs)		0.04 - 0.43
	Treatment Sequence 5	Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	08-01-2014/ 8:32	442 (H, ncs)		173 - 369
		Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	08-01-2014/ 8:32	0.53 (H, ncs)		0.04 - 0.43
		Neutrophils (10^9/L)	Period 2,Day -1/ 24 H Predose	08-01-2014/ 8:32	6.74 (H, ncs)		1.61 - 6.45
	Treatment Sequence 5	Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:20	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:20	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:20	14.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:20	100.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 5	Sodium (mmol/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:22	135.5 (L, ncs)		136.0 - 146.0
		Protein (mL/min/1.73m2)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:22	64.7 (L, ncs)		66.0 - 83.0
	Treatment Sequence 5	Leukocytes (uL)	Period 3,Day -1/ 24 H Predose	13-02-2014/13 :52	25.00 (H, ncs)		0.00 - 9.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 5	Chloride (mmol/L)	Follow-Up	27-02-2014/10:45	100.5 (L, ncs)	-2.5	101.0 - 109.0
		Neutrophils/Leukocytes (%)	Follow-Up	27-02-2014/10:45	73.2 (H, ncs)	-4	37.9 - 70.5
		Platelets (10^9/L)	Follow-Up	27-02-2014/10:45	375 (H, ncs)	-8	173 - 369
		Sodium (mmol/L)	Follow-Up	27-02-2014/10:45	133.6 (L, ncs)	-4.4	136.0 - 146.0
		Protein (mL/min/1.73m2)	Follow-Up	27-02-2014/10:45	63.1 (L, ncs)	-6.6	66.0 - 83.0
		Lymphocytes/Leukocytes (%)	Follow-Up	27-02-2014/10:45	16.3 (L, ncs)	2.2	17.8 - 48.5
	Treatment Sequence 3	Chloride (mmol/L)	Screening	25-11-2013/7:51	100.0 (L, ncs)		101.0 - 109.0
		Monocytes/Leukocytes (%)	Screening	25-11-2013/7:51	14.3 (H, ncs)		5.3 - 14.2
	Treatment Sequence 3	Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/8:16	21.6 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/8:16	97.6 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/8:16	132.3 (L, ncs)		136.0 - 146.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:16	3.85 (L, ncs)		4.02 - 5.08
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:16	18.4 (H, ncs)		1.6 - 17.6
		Lymphocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:16	17.1 (L, ncs)		17.8 - 48.5
		Lymphocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:16	0.95 (L, ncs)		0.99 - 2.89
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:16	2.42 (L, ncs)		2.80 - 7.20
	Treatment Sequence 3	Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:44	3.89 (L, ncs)		4.02 - 5.08
	Treatment Sequence 3	Sodium (mmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:27	135.7 (L, ncs)		136.0 - 146.0
		Erythrocytes (10^12/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:27	3.95 (L, ncs)		4.02 - 5.08
	Treatment Sequence 3	Erythrocytes (uL)	Follow-Up	05-03-2014/10 :16	10.00 (H, ncs)	10	0.00 - 5.00
	Treatment Sequence 3	Erythrocytes (10^12/L)	Follow-Up	05-03-2014/10 :22	3.88 (L, ncs)	-0.2	4.02 - 5.08
		Lymphocytes/Leukocytes (%)	Follow-Up	05-03-2014/10 :22	16.8 (L, ncs)	-5.5	17.8 - 48.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Monocytes (10^9/L)	Follow-Up	05-03-2014/10:22	0.96 (H, ncs)	0.18	0.27 - 0.91
		Monocytes/Leukocytes (%)	Follow-Up	05-03-2014/10:22	15.5 (H, ncs)	1.2	5.3 - 14.2
	Treatment Sequence 2	Eosinophils (10^9/L)	Screening	25-11-2013/9:25	0.50 (H, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Screening	25-11-2013/9:25	10.9 (H, ncs)		0.6 - 7.9
	Treatment Sequence 2	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/8:56	99.8 (L, ncs)		101.0 - 109.0
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/8:56	0.64 (H, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	01-12-2013/8:56	11.4 (H, ncs)		0.6 - 7.9
	Treatment Sequence 2	Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/8:40	100.9 (L, ncs)		101.0 - 109.0
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/8:40	62.2 (L, ncs)		62.7 - 150.8
		Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/8:40	0.54 (H, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	06-01-2014/8:40	10.7 (H, ncs)		0.6 - 7.9

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 2	Opiate	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:54	POSITIVE (H, ncs)		
	Treatment Sequence 2	Bilirubin (umol/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:56	4.6 (L, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:56	99.9 (L, ncs)		101.0 - 109.0
		Eosinophils (10^9/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:56	0.48 (H, ncs)		0.04 - 0.43
		Eosinophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:56	9.8 (H, ncs)		0.6 - 7.9
	Treatment Sequence 2	Chloride (mmol/L)	Follow-Up	04-03-2014/ 9:22	99.5 (L, ncs)	-1.8	101.0 - 109.0
		Thyroxine (nmol/L)	Follow-Up	04-03-2014/ 9:22	61.1 (L, ncs)	-9.5	62.7 - 150.8
		Eosinophils/Leukocytes (%)	Follow-Up	04-03-2014/ 9:22	8.0 (H, ncs)	-2.9	0.6 - 7.9
1	Treatment Sequence 6	Creatine Kinase (IU/L)	Screening	25-11-2013/11 :05	182.9 (H, ncs)		0.0 - 171.0
	Treatment Sequence 6	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 7:52	99.0 (L, ncs)		101.0 - 109.0
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 7:52	5.86 (H, ncs)		4.12 - 5.74

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 7:52	7.86 (H, ncs)		2.80 - 7.20
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 7:52	536.9 (H, ncs)		0.0 - 171.0
	Treatment Sequence 6	Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	01-12-2013/16 :52	412.1 (H, ncs)		0.0 - 171.0
	Treatment Sequence 6	Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:33	364.9 (H, ncs)		0.0 - 171.0
	Treatment Sequence 6	Chloride (mmol/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:35	99.2 (L, ncs)		101.0 - 109.0
		Erythrocytes (10^12/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:35	5.83 (H, ncs)		4.12 - 5.74
	Treatment Sequence 6	Thyroxine (nmol/L)	Follow-Up	25-02-2014/10 :55	61.2 (L, ncs)	-4.8	62.7 - 150.8
		Erythrocytes (10^12/L)	Follow-Up	25-02-2014/10 :55	5.76 (H, ncs)	0.17	4.12 - 5.74
	Treatment Sequence 4	Sodium (mmol/L)	Screening	26-11-2013/ 8:09	134.7 (L, ncs)		136.0 - 146.0
	Treatment Sequence 4	Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:10	135.5 (L, ncs)		136.0 - 146.0
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:10	4.00 (L, ncs)		4.02 - 5.08

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:10	230.4 (H, ncs)		0.0 - 145.0
	Treatment Sequence 4	Sodium (mmol/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/12 :17	134.1 (L, ncs)		136.0 - 146.0
		Erythrocytes (10^12/L)	Period 3,Day -1/ 24 H Predose	11-02-2014/12 :17	3.94 (L, ncs)		4.02 - 5.08
	Treatment Sequence 4	Erythrocytes (10^12/L)	Follow-Up	25-02-2014/ 7:46	3.95 (L, ncs)	-0.16	4.02 - 5.08
		Monocytes/Leukocytes (%)	Follow-Up	25-02-2014/ 7:46	15.7 (H, ncs)	3.4	5.3 - 14.2
	Treatment Sequence 4	Chloride (mmol/L)	Screening	26-11-2013/ 9:02	99.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Screening	26-11-2013/ 9:02	135.2 (L, ncs)		136.0 - 146.0
	Treatment Sequence 4	Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:26	6.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:26	25.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:26	POSITIVE (H, ncs)		
		Casts (/HPF)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:26	3 (H, ncs)		0 - 0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 4	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:29	99.9 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:29	133.9 (L, ncs)		136.0 - 146.0
	Treatment Sequence 4	Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:52	3.98 (L, ncs)		4.10 - 5.90
		Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:52	135.1 (L, ncs)		136.0 - 146.0
	Treatment Sequence 4	Chloride (mmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:44	98.7 (L, ncs)		101.0 - 109.0
		Sodium (mmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:44	133.8 (L, ncs)		136.0 - 146.0
	Treatment Sequence 4	Thyroxine (nmol/L)	Follow-Up	04-03-2014/ 8:24	60.6 (L, ncs)	-17.2	62.7 - 150.8
	Treatment Sequence 4	Leukocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 7:51	3.48 (L, ncs)		3.69 - 10.04
	Treatment Sequence 4	Thyroxine (nmol/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:25	62.3 (L, ncs)		62.7 - 150.8
		Lymphocytes (10^9/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:25	0.94 (L, ncs)		0.99 - 2.89
	Treatment Sequence 4	Erythrocytes (uL)	Follow-Up	11-03-2014/10 :03	10.00 (H, ncs)	10	0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 4	Sodium (mmol/L)	Follow-Up	11-03-2014/10:05	135.4 (L, ncs)	-1.2	136.0 - 146.0
		Erythrocytes (10^12/L)	Follow-Up	11-03-2014/10:05	3.93 (L, ncs)	-0.36	4.02 - 5.08
		Monocytes/Leukocytes (%)	Follow-Up	11-03-2014/10:05	14.7 (H, ncs)	3.8	5.3 - 14.2
	Treatment Sequence 2	Monocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:49	15.9 (H, ncs)		5.6 - 14.8
	Treatment Sequence 2	Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 7:46	25.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 2	Chloride (mmol/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 7:48	99.6 (L, ncs)		101.0 - 109.0
		Lymphocytes (10^9/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 7:48	1.00 (L, ncs)		1.08 - 3.00
		Monocytes/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 7:48	14.9 (H, ncs)		5.6 - 14.8
	Treatment Sequence 2	Thyroxine (nmol/L)	Follow-Up	07-03-2014/ 7:10	59.9 (L, ncs)	-13.5	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	07-03-2014/ 7:10	196.5 (H, ncs)	96.3	0.0 - 171.0
	Treatment Sequence 3	Leukocytes (uL)	Screening	27-11-2013/ 8:27	25.00 (H, ncs)		0.00 - 9.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 3	Glucose (mmol/L)	Screening	27-11-2013/ 8:36	3.80 (L, ncs)		4.10 - 5.90
	Treatment Sequence 3	Bacteria	Period 1,Day -1/ 24 H Predose	01-12-2013/ 7:44	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 7:44	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	01-12-2013/ 7:44	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 3	Leukocytes (/HPF)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:42	19.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	06-01-2014/ 8:42	100.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 3	Leukocytes (uL)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 8:59	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 3	Basophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	11-02-2014/ 9:01	1.5 (H, ncs)		0.2 - 1.3
	Treatment Sequence 3	Bacteria	Follow-Up	25-02-2014/ 9:17	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Follow-Up	25-02-2014/ 9:17	60.00 (H, ncs)	60	0.00 - 4.00
		Leukocytes (uL)	Follow-Up	25-02-2014/ 9:17	500.00 (H, ncs)	475	0.00 - 9.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Squamous Epithelial Cells (/HPF)	Follow-Up	25-02-2014/ 9:17	20 (H, ncs)	20	0 - 15
	Treatment Sequence 3	Urea (mmol/L)	Follow-Up	25-02-2014/ 9:18	2.70 (L, ncs)	-0.18	2.80 - 7.20
	Treatment Sequence 1	Bilirubin (umol/L)	Screening	27-11-2013/ 9:52	23.6 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Screening	27-11-2013/ 9:52	100.6 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	27-11-2013/ 9:52	3.96 (L, ncs)		4.10 - 5.90
		Direct Bilirubin (umol/L)	Screening	27-11-2013/ 9:52	4.1 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	27-11-2013/ 9:52	19.5 (H, ncs)		1.6 - 17.6
	Treatment Sequence 1	Alanine Aminotransferase (U/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:16	50.9 (H, ncs)		0.0 - 50.0
	Treatment Sequence 1	Alanine Aminotransferase (U/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:16	59.2 (H, ncs)		0.0 - 50.0
	Treatment Sequence 1	Alanine Aminotransferase (U/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/16 :24	59.9 (H, ncs)		0.0 - 50.0
	Treatment Sequence 1	Ketones (mmol/L)	Follow-Up	27-02-2014/ 9:40	0.5 (H, ncs)	0.5	0.0 - 0.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Bilirubin (umol/L)	Follow-Up	27-02-2014/ 9:46	23.7 (H, ncs)	0.1	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	27-02-2014/ 9:46	3.5 (H, ncs)	-0.6	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	27-02-2014/ 9:46	20.2 (H, ncs)	0.7	1.6 - 17.6
		Alanine Aminotransferase (U/L)	Follow-Up	27-02-2014/ 9:46	53.1 (H, ncs)	4.3	0.0 - 50.0
	Treatment Sequence 3	Glucose (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:06	4.08 (L, ncs)		4.10 - 5.90
	Treatment Sequence 3	Monocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:02	0.19 (L, ncs)		0.27 - 0.91
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:02	4.8 (L, ncs)		5.3 - 14.2
	Treatment Sequence 2	Bilirubin (umol/L)	Screening	27-11-2013/10 :25	33.1 (H, ncs)		5.0 - 21.0
		Hemoglobin (g/L)	Screening	27-11-2013/10 :25	147 (H, ncs)		111 - 146
		Direct Bilirubin (umol/L)	Screening	27-11-2013/10 :25	5.5 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	27-11-2013/10 :25	27.6 (H, ncs)		1.6 - 17.6

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Alanine Aminotransferase (U/L)	Screening	27-11-2013/10 :25	35.3 (H, ncs)		0.0 - 35.0
	Treatment Sequence 2	pH	Period 1,Day -1/ 24 H Predose	08-12-2013/ 7:50	8.0 (H, ncs)		4.8 - 7.4
	Treatment Sequence 2	Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 7:53	135.8 (L, ncs)		136.0 - 146.0
		Calcium (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 7:53	2.19 (L, ncs)		2.20 - 2.65
	Treatment Sequence 2	Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:08	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 2	Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:10	21.6 (H, ncs)		5.0 - 21.0
		Calcium (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:10	2.19 (L, ncs)		2.20 - 2.65
		Direct Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:10	3.6 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:10	18.0 (H, ncs)		1.6 - 17.6
		Leukocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:10	3.62 (L, ncs)		3.69 - 10.04
	Treatment Sequence 2	Hemoglobin (g/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:08	148 (H, ncs)		111 - 146

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 2	pH	Follow-Up	05-03-2014/ 9:37	8.0 (H, ncs)	1	4.8 - 7.4
	Treatment Sequence 2	Bilirubin (umol/L)	Follow-Up	05-03-2014/ 9:40	24.4 (H, ncs)	3.7	5.0 - 21.0
		Hemoglobin (g/L)	Follow-Up	05-03-2014/ 9:40	151 (H, ncs)	4	111 - 146
		Direct Bilirubin (umol/L)	Follow-Up	05-03-2014/ 9:40	4.3 (H, ncs)	-1.2	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	05-03-2014/ 9:40	20.1 (H, ncs)	-7.5	1.6 - 17.6
		Urea (mmol/L)	Follow-Up	05-03-2014/ 9:40	2.40 (L, ncs)	-0.49	2.80 - 7.20
	Treatment Sequence 4	Leukocytes (uL)	Screening	27-11-2013/10 :55	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 4	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:32	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:32	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:32	27.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:32	500.00 (H, ncs)		0.00 - 9.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 4	Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:35	135.7 (L, ncs)		136.0 - 146.0
	Treatment Sequence 4	Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	15-12-2013/18 :49	30.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/18 :49	500.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 4	Leukocytes (uL)	Follow-Up	03-01-2014/10 :10	25.00 (H, ncs)	0	0.00 - 9.00
	Treatment Sequence 4	Bilirubin (umol/L)	Follow-Up	03-01-2014/10 :19	4.8 (L, ncs)	-2.4	5.0 - 21.0
		Alanine Aminotransferase (U/L)	Follow-Up	03-01-2014/10 :19	49.2 (H, ncs)	37.8	0.0 - 35.0
	Treatment Sequence 2	Ketones (mmol/L)	Screening	27-11-2013/10 :52	0.5 (H, ncs)		0.0 - 0.5
	Treatment Sequence 2	Creatine Kinase (IU/L)	Screening	27-11-2013/10 :54	372.7 (H, ncs)		0.0 - 171.0
	Treatment Sequence 2	Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:31	0.5 (H, ncs)		0.0 - 0.5
	Treatment Sequence 2	Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:34	174.2 (H, ncs)		0.0 - 171.0
	Treatment Sequence 2	Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:23	60.0 (L, ncs)		62.7 - 150.8

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 2	Thyroxine (nmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:25	56.2 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:25	291.3 (H, ncs)		0.0 - 171.0
		Triiodothyronine (nmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:25	4.06 (H, ncs)		0.89 - 2.44
	Treatment Sequence 2	Thyroxine (nmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/19 :12	56.3 (L, ncs)		62.7 - 150.8
		Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/19 :12	297.8 (H, ncs)		0.0 - 171.0
		Triiodothyronine (nmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/19 :12	2.83 (H, ncs)		0.89 - 2.44
	Treatment Sequence 2	Thyroxine (nmol/L)	Follow-Up	04-03-2014/11 :25	57.5 (L, ncs)	-14.8	62.7 - 150.8
		Creatine Kinase (IU/L)	Follow-Up	04-03-2014/11 :25	251.5 (H, ncs)	-121.2	0.0 - 171.0
	Treatment Sequence 3	pH	Screening	28-11-2013/10 :18	8.0 (H, ncs)		4.8 - 7.4
	Treatment Sequence 3	Chloride (mmol/L)	Screening	28-11-2013/10 :21	100.4 (L, ncs)		101.0 - 109.0
	Treatment Sequence 3	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	100.5 (L, ncs)		101.0 - 109.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Neutrophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	73.8 (H, ncs)		38.2 - 71.5
		Leukocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	11.60 (H, ncs)		3.19 - 8.71
		Lymphocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	16.6 (L, ncs)		18.3 - 48.1
		Neutrophils (10^9/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	8.57 (H, ncs)		1.46 - 5.85
		Monocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	1.04 (H, ncs)		0.30 - 0.92
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	2.64 (L, ncs)		2.80 - 7.20
		Eosinophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	03-12-2013/ 8:44	0.5 (L, ncs)		0.6 - 8.4
	Treatment Sequence 3	Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	08-01-2014/ 8:34	100.9 (L, ncs)		101.0 - 109.0
		Hemoglobin (g/L)	Period 2,Day -1/ 24 H Predose	08-01-2014/ 8:34	168 (H, ncs)		126 - 165
	Treatment Sequence 3	Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:40	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:42	642.0 (H, ncs)		0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/16 :27	1254.8 (H, ncs)		0.0 - 171.0
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	14-02-2014/ 7:10	2263.9 (H, ncs)		0.0 - 171.0
		Creatine Kinase MB (IU/L)	Period 3,Day -1/ 24 H Predose	14-02-2014/ 7:10	32.0 (H, ncs)		0.0 - 24.0
	Treatment Sequence 3	pH	Follow-Up	27-02-2014/ 8:08	8.0 (H, ncs)	0	4.8 - 7.4
	Treatment Sequence 4	Chloride (mmol/L)	Screening	28-11-2013/10 :31	100.1 (L, ncs)		101.0 - 109.0
	Treatment Sequence 4	Bilirubin (umol/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:27	21.4 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:27	100.8 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:27	4.0 (H, ncs)		0.0 - 3.4
		Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/ 8:27	298.1 (H, ncs)		0.0 - 171.0
	Treatment Sequence 4	Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	13-02-2014/16 :36	226.7 (H, ncs)		0.0 - 171.0
	Treatment Sequence 4	Creatine Kinase (IU/L)	Follow-Up	27-02-2014/ 8:13	171.3 (H, ncs)	41.5	0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 5	Chloride (mmol/L)	Screening	29-11-2013/ 8:15	98.5 (L, ncs)		101.0 - 109.0
		Urea (mmol/L)	Screening	29-11-2013/ 8:15	2.61 (L, ncs)		2.80 - 7.20
	Treatment Sequence 5	Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:52	135.8 (L, ncs)		136.0 - 146.0
	Treatment Sequence 5	Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 9:05	99.2 (L, ncs)		101.0 - 109.0
	Treatment Sequence 5	Bilirubin (umol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:12	21.2 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:12	3.6 (H, ncs)		0.0 - 3.4
		Gamma Glutamyl Transferase (U/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:12	57.4 (H, ncs)		0.0 - 55.0
	Treatment Sequence 5	Chloride (mmol/L)	Follow-Up	04-03-2014/ 7:39	99.5 (L, ncs)	1	101.0 - 109.0
		Thyroxine (nmol/L)	Follow-Up	04-03-2014/ 7:39	60.5 (L, ncs)	-11.8	62.7 - 150.8
		Gamma Glutamyl Transferase (U/L)	Follow-Up	04-03-2014/ 7:39	55.3 (H, ncs)	7.5	0.0 - 55.0
	Treatment Sequence 6	Protein (mL/min/1.73m2)	Screening	29-11-2013/ 8:55	65.8 (L, ncs)		66.0 - 83.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Creatine Kinase (IU/L)	Screening	29-11-2013/ 8:55	461.4 (H, ncs)		0.0 - 145.0
	Treatment Sequence 6	Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:58	231.8 (H, ncs)		0.0 - 145.0
	Treatment Sequence 6	Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:31	4.9 (L, ncs)		5.0 - 21.0
		Hemoglobin (g/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:31	110 (L, ncs)		111 - 146
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:31	3.99 (L, ncs)		4.02 - 5.08
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:31	147.7 (H, ncs)		0.0 - 145.0
	Treatment Sequence 6	Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 8:09	145.3 (H, ncs)		0.0 - 145.0
	Treatment Sequence 6	Hemoglobin (g/L)	Follow-Up	06-03-2014/ 8:36	106 (L, ncs)	-20	111 - 146
		Leukocytes (10^9/L)	Follow-Up	06-03-2014/ 8:36	3.65 (L, ncs)	-0.85	3.69 - 10.04
		Urea (mmol/L)	Follow-Up	06-03-2014/ 8:36	2.70 (L, ncs)	-1.03	2.80 - 7.20
		Hematocrit (L/L)	Follow-Up	06-03-2014/ 8:36	0.33 (L, ncs)	-0.05	0.35 - 0.44

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Chloride (mmol/L)	Screening	29-11-2013/11:25	99.5 (L, ncs)		101.0 - 109.0
		Glucose (mmol/L)	Screening	29-11-2013/11:25	3.87 (L, ncs)		4.10 - 5.90
		Sodium (mmol/L)	Screening	29-11-2013/11:25	134.7 (L, ncs)		136.0 - 146.0
	Treatment Sequence 1	Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:35	20.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:35	100.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 1	Hemoglobin (g/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:08	107 (L, ncs)		111 - 146
	Treatment Sequence 1	Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:03	8.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:03	250.00 (H, ncs)		0.00 - 5.00
		Leukocytes (/HPF)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:03	10.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:03	100.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 1	Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:05	62.0 (L, ncs)		62.7 - 150.8

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Hemoglobin (g/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 8:14	104 (L, ncs)		111 - 146
		Thyroxine (nmol/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 8:14	56.8 (L, ncs)		62.7 - 150.8
		Hematocrit (L/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 8:14	0.34 (L, ncs)		0.35 - 0.44
	Treatment Sequence 1	Bacteria	Follow-Up	06-03-2014/ 8:24	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Follow-Up	06-03-2014/ 8:24	15.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	06-03-2014/ 8:24	25.00 (H, ncs)	25	0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Follow-Up	06-03-2014/ 8:24	30 (H, ncs)		0 - 15
		Ketones (mmol/L)	Follow-Up	06-03-2014/ 8:24	0.5 (H, ncs)	0.5	0.0 - 0.5
	Treatment Sequence 1	Hemoglobin (g/L)	Follow-Up	06-03-2014/ 8:28	100 (L, ncs)	-13	111 - 146
		Thyroxine (nmol/L)	Follow-Up	06-03-2014/ 8:28	62.0 (L, ncs)	-0.8	62.7 - 150.8
		Hematocrit (L/L)	Follow-Up	06-03-2014/ 8:28	0.33 (L, ncs)	-0.03	0.35 - 0.44

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Leukocytes (/HPF)	Follow-Up	10-03-2014/ 7:15	10.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Follow-Up	10-03-2014/ 7:15	100.00 (H, ncs)	100	0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Follow-Up	10-03-2014/ 7:15	26 (H, ncs)		0 - 15
	Treatment Sequence 2	Ketones (mmol/L)	Screening	29-11-2013/11 :56	0.5 (H, ncs)		0.0 - 0.5
	Treatment Sequence 2	Urea (mmol/L)	Screening	29-11-2013/11 :59	2.10 (L, ncs)		2.80 - 7.20
	Treatment Sequence 2	Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:07	135.7 (L, ncs)		136.0 - 146.0
	Treatment Sequence 2	Erythrocytes (/HPF)	Follow-Up	27-12-2013/ 9:23	5.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Follow-Up	27-12-2013/ 9:23	25.00 (H, ncs)	25	0.00 - 5.00
		Leukocytes (uL)	Follow-Up	27-12-2013/ 9:23	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 2	Sodium (mmol/L)	Follow-Up	27-12-2013/ 9:24	135.3 (L, ncs)	-1.4	136.0 - 146.0
		Calcium (mmol/L)	Follow-Up	27-12-2013/ 9:24	2.12 (L, ncs)	-0.22	2.20 - 2.65

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Protein (mL/min/1.73m2)	Follow-Up	27-12-2013/ 9:24	61.4 (L, ncs)	-7.3	66.0 - 83.0
	Treatment Sequence 3	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 8:22	100.6 (L, ncs)		101.0 - 109.0
	Treatment Sequence 3	Protein (mL/min/1.73m2)	Period 2,Day -1/ 24 H Predose	22-01-2014/ 8:27	64.9 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	22-01-2014/ 8:27	195.1 (H, ncs)		0.0 - 171.0
		Gamma Glutamyl Transferase (U/L)	Period 2,Day -1/ 24 H Predose	22-01-2014/ 8:27	55.6 (H, ncs)		0.0 - 55.0
	Treatment Sequence 3	Protein (mL/min/1.73m2)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:56	61.6 (L, ncs)		66.0 - 83.0
		Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:56	192.1 (H, ncs)		0.0 - 171.0
	Treatment Sequence 3	Chloride (mmol/L)	Follow-Up	13-03-2014/ 7:19	99.8 (L, ncs)	-1.6	101.0 - 109.0
		Calcium (mmol/L)	Follow-Up	13-03-2014/ 7:19	2.18 (L, ncs)	-0.17	2.20 - 2.65
		Protein (mL/min/1.73m2)	Follow-Up	13-03-2014/ 7:19	60.7 (L, ncs)	-8.6	66.0 - 83.0
		Creatine Kinase (IU/L)	Follow-Up	13-03-2014/ 7:19	213.2 (H, ncs)	55.2	0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 4	Basophils/Leukocytes (%)	Screening	02-12-2013/ 9:44	1.8 (H, ncs)		0.0 - 1.0
		Basophils (10^9/L)	Screening	02-12-2013/ 9:44	0.08 (H, ncs)		0.01 - 0.07
	Treatment Sequence 4	Eosinophils (10^9/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:32	0.52 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:32	9.5 (H, ncs)		0.6 - 8.4
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:32	1.5 (H, ncs)		0.0 - 1.0
		Basophils (10^9/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:32	0.08 (H, ncs)		0.01 - 0.07
	Treatment Sequence 4	Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:39	10.00 (H, ncs)		0.00 - 5.00
		Leukocytes (uL)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:39	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 4	Eosinophils (10^9/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:41	0.55 (H, ncs)		0.03 - 0.50
		Eosinophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:41	10.0 (H, ncs)		0.6 - 8.4
		Basophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:41	1.6 (H, ncs)		0.0 - 1.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Alanine Aminotransferase (U/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:41	60.4 (H, ncs)		0.0 - 50.0
		Basophils (10^9/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 9:41	0.09 (H, ncs)		0.01 - 0.07
	Treatment Sequence 4	Eosinophils (10^9/L)	Follow-Up	05-03-2014/11 :09	0.91 (H, ncs)	0.62	0.03 - 0.50
		Eosinophils/Leukocytes (%)	Follow-Up	05-03-2014/11 :09	14.7 (H, ncs)	8.2	0.6 - 8.4
		Basophils/Leukocytes (%)	Follow-Up	05-03-2014/11 :09	1.9 (H, ncs)	0.1	0.0 - 1.0
		Basophils (10^9/L)	Follow-Up	05-03-2014/11 :09	0.12 (H, ncs)	0.04	0.01 - 0.07
	Treatment Sequence 5	Basophils/Leukocytes (%)	Screening	02-12-2013/ 9:59	1.6 (H, ncs)		0.2 - 1.3
		Basophils (10^9/L)	Screening	02-12-2013/ 9:59	0.08 (H, ncs)		0.01 - 0.07
	Treatment Sequence 5	Sodium (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 7:38	135.7 (L, ncs)		136.0 - 146.0
		Monocytes/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 7:38	15.4 (H, ncs)		5.3 - 14.2
	Treatment Sequence 5	Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 7:42	3.88 (L, ncs)		4.02 - 5.08

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Monocytes (10^9/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 7:42	0.93 (H, ncs)		0.27 - 0.91
		Monocytes/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 7:42	16.7 (H, ncs)		5.3 - 14.2
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 7:42	2.66 (L, ncs)		2.80 - 7.20
	Treatment Sequence 5	Neutrophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:19	73.3 (H, ncs)		37.9 - 70.5
		Erythrocytes (10^12/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:19	3.86 (L, ncs)		4.02 - 5.08
		Lymphocytes/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:19	15.5 (L, ncs)		17.8 - 48.5
		Neutrophils (10^9/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:19	6.73 (H, ncs)		1.61 - 6.45
	Treatment Sequence 5	Erythrocytes (/HPF)	Follow-Up	04-03-2014/ 9:47	5.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Follow-Up	04-03-2014/ 9:47	25.00 (H, ncs)	25	0.00 - 5.00
	Treatment Sequence 5	Platelets (10^9/L)	Follow-Up	04-03-2014/ 9:50	374 (H, ncs)	84	173 - 369
		Erythrocytes (10^12/L)	Follow-Up	04-03-2014/ 9:50	3.91 (L, ncs)	-0.16	4.02 - 5.08

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Urea (mmol/L)	Follow-Up	04-03-2014/ 9:50	2.61 (L, ncs)	-0.9	2.80 - 7.20
	Treatment Sequence 2	Leukocytes (/HPF)	Screening	02-12-2013/11 :11	15.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Screening	02-12-2013/11 :11	100.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 2	Platelets (10^9/L)	Screening	02-12-2013/11 :14	437 (H, ncs)		173 - 369
		Basophils (10^9/L)	Screening	02-12-2013/11 :14	0.08 (H, ncs)		0.01 - 0.07
	Treatment Sequence 2	Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:25	8.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:25	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 2	Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:27	378 (H, ncs)		173 - 369
	Treatment Sequence 2	Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 9:29	50.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 2	Platelets (10^9/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 9:31	428 (H, ncs)		173 - 369
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 9:31	1.5 (H, ncs)		0.2 - 1.3

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Basophils (10^9/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 9:31	0.09 (H, ncs)		0.01 - 0.07
	Treatment Sequence 2	Platelets (10^9/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/10 :42	446 (H, ncs)		173 - 369
		Basophils (10^9/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/10 :42	0.09 (H, ncs)		0.01 - 0.07
	Treatment Sequence 2	Leukocytes (/HPF)	Follow-Up	07-03-2014/10 :20	8.00 (H, ncs)	-7	0.00 - 4.00
		Leukocytes (uL)	Follow-Up	07-03-2014/10 :20	25.00 (H, ncs)	-75	0.00 - 9.00
	Treatment Sequence 2	Platelets (10^9/L)	Follow-Up	07-03-2014/10 :22	397 (H, ncs)	-40	173 - 369
		Neutrophils (10^9/L)	Follow-Up	07-03-2014/10 :22	6.46 (H, ncs)	2.69	1.61 - 6.45
		Monocytes (10^9/L)	Follow-Up	07-03-2014/10 :22	1.23 (H, ncs)	0.65	0.27 - 0.91
	Treatment Sequence 5	Bilirubin (umol/L)	Screening	03-12-2013/10 :12	40.0 (H, ncs)		5.0 - 21.0
		Glucose (mmol/L)	Screening	03-12-2013/10 :12	4.07 (L, ncs)		4.10 - 5.90
		Direct Bilirubin (umol/L)	Screening	03-12-2013/10 :12	7.4 (H, ncs)		0.0 - 3.4

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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EMR 200125-002
Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Indirect Bilirubin (umol/L)	Screening	03-12-2013/10:12	32.6 (H, ncs)		1.6 - 17.6
		Leukocytes (10^9/L)	Screening	03-12-2013/10:12	3.66 (L, ncs)		3.69 - 10.04
	Treatment Sequence 5	Bilirubin (umol/L)	Screening	06-12-2013/8:14	26.8 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	06-12-2013/8:14	5.1 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	06-12-2013/8:14	21.7 (H, ncs)		1.6 - 17.6
	Treatment Sequence 5	Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/8:18	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 5	Sodium (mmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/8:20	135.0 (L, ncs)		136.0 - 146.0
		Thyroxine (nmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/8:20	55.3 (L, ncs)		62.7 - 150.8
	Treatment Sequence 5	Neutrophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	23-02-2014/10:30	33.9 (L, ncs)		37.9 - 70.5
		Eosinophils (10^9/L)	Period 3,Day -1/ 24 H Predose	23-02-2014/10:30	0.49 (H, ncs)		0.04 - 0.43
		Leukocytes (10^9/L)	Period 3,Day -1/ 24 H Predose	23-02-2014/10:30	3.55 (L, ncs)		3.69 - 10.04

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Neutrophils (10^9/L)	Period 3,Day -1/ 24 H Predose	23-02-2014/10 :30	1.20 (L, ncs)		1.61 - 6.45
		Eosinophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	23-02-2014/10 :30	13.8 (H, ncs)		0.6 - 7.9
	Treatment Sequence 5	Thyroxine (nmol/L)	Follow-Up	10-03-2014/ 8:37	47.0 (L, ncs)	-18.2	62.7 - 150.8
		Protein (mL/min/1.73m2)	Follow-Up	10-03-2014/ 8:37	65.7 (L, ncs)	-5.9	66.0 - 83.0
		Eosinophils (10^9/L)	Follow-Up	10-03-2014/ 8:37	0.51 (H, ncs)	0.27	0.04 - 0.43
		Eosinophils/Leukocytes (%)	Follow-Up	10-03-2014/ 8:37	10.7 (H, ncs)	4.1	0.6 - 7.9
	Treatment Sequence 6	Erythrocytes (/HPF)	Screening	04-12-2013/ 9:26	5.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Screening	04-12-2013/ 9:26	50.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 6	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 7:52	50.00 (H, ncs)		0.00 - 5.00
		Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 7:52	0.5 (H, ncs)		0.0 - 0.5
	Treatment Sequence 6	Erythrocytes (/HPF)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:10	8.00 (H, ncs)		0.00 - 3.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:10	50.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 6	Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:13	43.4 (H, ncs)		0.0 - 35.0
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:13	38.1 (H, ncs)		0.0 - 35.0
	Treatment Sequence 6	Erythrocytes (/HPF)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 9:16	5.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 9:16	25.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 6	Erythrocytes (/HPF)	Follow-Up	06-03-2014/ 7:18	6.00 (H, ncs)	1	0.00 - 3.00
		Erythrocytes (uL)	Follow-Up	06-03-2014/ 7:18	25.00 (H, ncs)	-25	0.00 - 5.00
		Bacteria	Follow-Up	06-03-2014/ 7:18	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Follow-Up	06-03-2014/ 7:18	20.00 (H, ncs)	17	0.00 - 4.00
		Leukocytes (uL)	Follow-Up	06-03-2014/ 7:18	100.00 (H, ncs)	100	0.00 - 9.00
		Squamous Epithelial Cells (/HPF)	Follow-Up	06-03-2014/ 7:18	20 (H, ncs)	18	0 - 15

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 6	Chloride (mmol/L)	Follow-Up	06-03-2014/ 7:23	109.3 (H, ncs)	6.3	101.0 - 109.0
		Hemoglobin (g/L)	Follow-Up	06-03-2014/ 7:23	109 (L, ncs)	-9	111 - 146
		Calcium (mmol/L)	Follow-Up	06-03-2014/ 7:23	2.19 (L, ncs)	-0.11	2.20 - 2.65
	Treatment Sequence 1	Erythrocytes (uL)	Screening	04-12-2013/10 :12	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 1	Urea (mmol/L)	Screening	04-12-2013/10 :15	2.71 (L, ncs)		2.80 - 7.20
	Treatment Sequence 1	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:02	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 1	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:04	100.0 (L, ncs)		101.0 - 109.0
	Treatment Sequence 1	Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:01	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 1	Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:03	26.8 (H, ncs)		5.0 - 21.0
		Chloride (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:03	100.3 (L, ncs)		101.0 - 109.0
		Direct Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:03	4.7 (H, ncs)		0.0 - 3.4

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Indirect Bilirubin (umol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 8:03	22.1 (H, ncs)		1.6 - 17.6
	Treatment Sequence 1	pH	Period 3,Day -1/ 24 H Predose	18-02-2014/11 :52	8.0 (H, ncs)		4.8 - 7.4
	Treatment Sequence 1	Thyroxine (nmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/11 :54	60.3 (L, ncs)		62.7 - 150.8
	Treatment Sequence 1	Erythrocytes (uL)	Follow-Up	05-03-2014/ 9:17	10.00 (H, ncs)	0	0.00 - 5.00
	Treatment Sequence 1	Thyroxine (nmol/L)	Follow-Up	05-03-2014/ 9:20	58.7 (L, ncs)	-7.1	62.7 - 150.8
	eatment Sequence 6	Chloride (mmol/L)	Screening	04-12-2013/10 :21	99.7 (L, ncs)		101.0 - 109.0
	Treatment Sequence 6	Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:14	21.2 (H, ncs)		5.0 - 21.0
		Hemoglobin (g/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:14	169 (H, ncs)		126 - 165
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:14	4.0 (H, ncs)		0.0 - 3.4
		Hematocrit (L/L)	Period 1,Day -1/ 24 H Predose	08-12-2013/ 8:14	0.49 (H, ncs)		0.38 - 0.48
	Treatment Sequence 6	Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 7:56	0.5 (H, ncs)		0.0 - 0.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 6	Protein (mL/min/1.73m2)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 7:58	64.0 (L, ncs)		66.0 - 83.0
		Basophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	13-01-2014/ 7:58	1.3 (H, ncs)		0.0 - 1.0
	Treatment Sequence 6	Chloride (mmol/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:30	100.7 (L, ncs)		101.0 - 109.0
		Hemoglobin (g/L)	Period 3,Day -1/ 24 H Predose	18-02-2014/ 8:30	167 (H, ncs)		126 - 165
	Treatment Sequence 6	Urea (mmol/L)	Follow-Up	04-03-2014/ 8:10	7.95 (H, ncs)	1.54	2.80 - 7.20
	reatment Sequence 5	Amylase (IU/L)	Screening	05-12-2013/ 8:10	19.3 (L, ncs)		28.0 - 100.0
		Protein (mL/min/1.73m2)	Screening	05-12-2013/ 8:10	65.2 (L, ncs)		66.0 - 83.0
	Treatment Sequence 5	Amylase (IU/L)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 7:20	22.1 (L, ncs)		28.0 - 100.0
		Neutrophils/Leukocytes (%)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 7:20	36.5 (L, ncs)		38.2 - 71.5
		Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 7:20	188.8 (H, ncs)		0.0 - 171.0
	Treatment Sequence 5	Erythrocytes (uL)	Period 2,Day -1/ 24 H Predose	22-01-2014/ 8:47	10.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 5	Amylase (IU/L)	Period 2,Day -1/ 24 H Predose	22-01-2014/ 8:49	17.8 (L, ncs)		28.0 - 100.0
	Treatment Sequence 5	Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:05	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 5	Amylase (IU/L)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:07	23.1 (L, ncs)		28.0 - 100.0
		Neutrophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:07	34.9 (L, ncs)		38.2 - 71.5
	Treatment Sequence 5	Amylase (IU/L)	Follow-Up	13-03-2014/ 7:32	22.3 (L, ncs)	3	28.0 - 100.0
		Bilirubin (umol/L)	Follow-Up	13-03-2014/ 7:32	4.6 (L, ncs)	-11.9	5.0 - 21.0
		Chloride (mmol/L)	Follow-Up	13-03-2014/ 7:32	99.8 (L, ncs)	-2	101.0 - 109.0
		Neutrophils/Leukocytes (%)	Follow-Up	13-03-2014/ 7:32	25.0 (L, ncs)	-13.9	38.2 - 71.5
		Protein (mL/min/1.73m2)	Follow-Up	13-03-2014/ 7:32	65.1 (L, ncs)	-0.1	66.0 - 83.0
		Lymphocytes/Leukocytes (%)	Follow-Up	13-03-2014/ 7:32	55.7 (H, ncs)	9.9	18.3 - 48.1
		Neutrophils (10^9/L)	Follow-Up	13-03-2014/ 7:32	1.05 (L, ncs)	-0.51	1.46 - 5.85

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Chloride (mmol/L)	Screening	05-12-2013/ 8:46	99.2 (L, ncs)		101.0 - 109.0
		Erythrocytes (uL)	Screening	05-12-2013/ 8:46	10.00 (H, ncs)		0.00 - 5.00
		Platelets (10^9/L)	Screening	05-12-2013/ 8:46	368 (H, ncs)		155 - 342
		Lymphocytes/Leukocytes (%)	Screening	05-12-2013/ 8:46	17.6 (L, ncs)		18.3 - 48.1
		Lymphocytes (10^9/L)	Screening	05-12-2013/ 8:46	0.98 (L, ncs)		1.08 - 3.00
		Urea (mmol/L)	Screening	05-12-2013/ 8:46	2.61 (L, ncs)		2.80 - 7.20
		Gamma Glutamyl Transferase (U/L)	Screening	05-12-2013/ 8:46	56.7 (H, ncs)		0.0 - 55.0
	Treatment Sequence 1	Ketones (mmol/L)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 7:46	0.5 (H, ncs)		0.0 - 0.5
	Treatment Sequence 1	Chloride (mmol/L)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 7:47	100.3 (L, ncs)		101.0 - 109.0
		Platelets (10^9/L)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 7:47	401 (H, ncs)		155 - 342
	Treatment Sequence 1	Ketones (mmol/L)	Period 2,Day -1/ 24 H Predose	22-01-2014/ 7:26	0.5 (H, ncs)		0.0 - 0.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 1	Erythrocytes (/HPF)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:49	6.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:49	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:49	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:49	8.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:49	25.00 (H, ncs)		0.00 - 9.00
		Ketones (mmol/L)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:49	0.5 (H, ncs)		0.0 - 0.5
		Protein (g/L)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:49	0.25 (H, ncs)		0.00 - 0.09
	Treatment Sequence 1	Thyroxine (nmol/L)	Period 3,Day -1/ 24 H Predose	27-02-2014/ 7:52	58.5 (L, ncs)		62.7 - 150.8
	Treatment Sequence 1	Erythrocytes (uL)	Follow-Up	13-03-2014/ 7:32	10.00 (H, ncs)	0	0.00 - 5.00
	Treatment Sequence 1	Chloride (mmol/L)	Follow-Up	13-03-2014/ 7:35	99.4 (L, ncs)	0.2	101.0 - 109.0
	Treatment Sequence 5	Glucose (mmol/L)	Screening	05-12-2013/ 9:35	4.01 (L, ncs)		4.10 - 5.90

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 5	Eosinophils (10^9/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:19	0.54 (H, ncs)		0.04 - 0.43
		Leukocytes (10^9/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:19	10.32 (H, ncs)		3.69 - 10.04
		Lymphocytes/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:19	16.8 (L, ncs)		17.8 - 48.5
		Neutrophils (10^9/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:19	7.15 (H, ncs)		1.61 - 6.45
		Urea (mmol/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:19	2.61 (L, ncs)		2.80 - 7.20
		Basophils/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:19	0.1 (L, ncs)		0.2 - 1.3
	Treatment Sequence 5	Erythrocytes (uL)	Follow-Up	13-03-2014/ 8:15	250.00 (H, ncs)	250	0.00 - 5.00
		Leukocytes (uL)	Follow-Up	13-03-2014/ 8:15	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 5	Thyroxine (nmol/L)	Follow-Up	13-03-2014/ 8:18	59.8 (L, ncs)	-8.1	62.7 - 150.8
	Treatment Sequence 5	Erythrocytes (uL)	Screening	05-12-2013/11 :03	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 5	Bilirubin (umol/L)	Screening	05-12-2013/11 :06	32.3 (H, ncs)		5.0 - 21.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Direct Bilirubin (umol/L)	Screening	05-12-2013/11 :06	4.7 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	05-12-2013/11 :06	27.6 (H, ncs)		1.6 - 17.6
	Treatment Sequence 5	Bilirubin (umol/L)	Screening	09-12-2013/ 7:28	26.1 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	09-12-2013/ 7:28	4.0 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Screening	09-12-2013/ 7:28	22.1 (H, ncs)		1.6 - 17.6
	Treatment Sequence 5	Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:53	25.7 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:53	4.1 (H, ncs)		0.0 - 3.4
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:53	21.6 (H, ncs)		1.6 - 17.6
	Treatment Sequence 5	Bilirubin (umol/L)	Follow-Up	30-12-2013/12 :08	30.1 (H, ncs)	4	5.0 - 21.0
		Direct Bilirubin (umol/L)	Follow-Up	30-12-2013/12 :08	4.2 (H, ncs)	0.2	0.0 - 3.4
		Indirect Bilirubin (umol/L)	Follow-Up	30-12-2013/12 :08	25.9 (H, ncs)	3.8	1.6 - 17.6

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 3	Chloride (mmol/L)	Screening	05-12-2013/11 :40	99.8 (L, ncs)		101.0 - 109.0
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 8:41	426.0 (H, ncs)		0.0 - 171.0
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/17 :11	396.8 (H, ncs)		0.0 - 171.0
	Treatment Sequence 3	Neutrophils/Leukocytes (%)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:35	37.7 (L, ncs)		38.2 - 71.5
		Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:35	5294.5 (H, ncs)		0.0 - 171.0
		Alanine Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:35	50.1 (H, ncs)		0.0 - 50.0
		Creatine Kinase MB (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:35	53.0 (H, ncs)		0.0 - 24.0
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:35	116.3 (H, ncs)		0.0 - 50.0
		Lactate Dehydrogenase (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/ 8:35	264.0 (H, ncs)		0.0 - 248.0
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/17 :54	4656.0 (H, ncs)		0.0 - 171.0
		Creatine Kinase MB (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/17 :54	49.4 (H, ncs)		0.0 - 24.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/17 :54	116.5 (H, ncs)		0.0 - 50.0
		Lactate Dehydrogenase (IU/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/17 :54	267.5 (H, ncs)		0.0 - 248.0
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 2,Day -1/ 24 H Predose	18-01-2014/ 8:38	1054.3 (H, ncs)		0.0 - 171.0
		Aspartate Aminotransferase (U/L)	Period 2,Day -1/ 24 H Predose	18-01-2014/ 8:38	57.4 (H, ncs)		0.0 - 50.0
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/ 9:20	353.6 (H, ncs)		0.0 - 171.0
	Treatment Sequence 3	Creatine Kinase (IU/L)	Period 3,Day -1/ 24 H Predose	20-02-2014/16 :50	337.2 (H, ncs)		0.0 - 171.0
	Treatment Sequence 4	Bilirubin (umol/L)	Screening	05-12-2013/11 :53	22.0 (H, ncs)		5.0 - 21.0
		Direct Bilirubin (umol/L)	Screening	05-12-2013/11 :53	4.9 (H, ncs)		0.0 - 3.4
		Thyrotropin (mU/L)	Screening	05-12-2013/11 :53	0.32 (L, ncs)		0.35 - 4.94
	Treatment Sequence 4	Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	15-01-2014/10 :35	4.09 (L, ncs)		4.10 - 5.90
	Treatment Sequence 4	Thyrotropin (mU/L)	Follow-Up	06-03-2014/10 :30	0.23 (L, ncs)	-0.44	0.35 - 4.94

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
	Treatment Sequence 3	Erythrocytes (10^12/L)	Screening	06-12-2013/10:17	3.99 (L, ncs)		4.02 - 5.08
	Treatment Sequence 3	Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	5.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	50.00 (H, ncs)		0.00 - 5.00
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	3.99 (L, ncs)		4.02 - 5.08
		Protein (mL/min/1.73m2)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	64.7 (L, ncs)		66.0 - 83.0
		Bacteria	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	18.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	500.00 (H, ncs)		0.00 - 9.00
		Urea (mmol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:20	2.73 (L, ncs)		2.80 - 7.20
	Treatment Sequence 3	Bacteria	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:56	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:56	8.00 (H, ncs)		0.00 - 4.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Leukocytes (uL)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:56	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 3	Glucose (mmol/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 8:57	4.03 (L, ncs)		4.10 - 5.90
	Treatment Sequence 3	Leukocytes (uL)	Period 3,Day -1/ 24 H Predose	25-02-2014/20 :16	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 3	Leukocytes (uL)	Follow-Up	12-03-2014/ 7:35	25.00 (H, ncs)	25	0.00 - 9.00
	Treatment Sequence 3	Erythrocytes (10^12/L)	Follow-Up	12-03-2014/ 8:08	4.01 (L, ncs)	0.02	4.02 - 5.08
	Treatment Sequence 6	Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 8:30	10.00 (H, ncs)		0.00 - 5.00
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	17-12-2013/ 8:30	0.25 (H, ncs)		0.00 - 0.09
	Treatment Sequence 6	Creatinine (umol/L)	Screening	06-12-2013/11 :26	50.8 (L, ncs)		59.0 - 104.0
	Treatment Sequence 6	Creatinine (umol/L)	Period 1,Day -1/ 24 H Predose	10-12-2013/ 9:05	56.6 (L, ncs)		59.0 - 104.0
	Treatment Sequence 6	Erythrocytes (uL)	Follow-Up	26-02-2014/ 9:14	10.00 (H, ncs)	10	0.00 - 5.00
	Treatment Sequence 6	Glucose (mmol/L)	Follow-Up	26-02-2014/ 9:18	3.97 (L, ncs)	-0.21	4.10 - 5.90

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Thyroxine (nmol/L)	Follow-Up	26-02-2014/ 9:18	59.4 (L, ncs)	-11.2	62.7 - 150.8
		Creatinine (umol/L)	Follow-Up	26-02-2014/ 9:18	56.1 (L, ncs)	5.3	59.0 - 104.0
	Treatment Sequence 1	Erythrocytes (uL)	Screening	09-12-2013/11 :17	10.00 (H, ncs)		0.00 - 5.00
		Bacteria	Screening	09-12-2013/11 :17	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Screening	09-12-2013/11 :17	10.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Screening	09-12-2013/11 :17	25.00 (H, ncs)		0.00 - 9.00
	Treatment Sequence 1	Hemoglobin (g/L)	Screening	09-12-2013/11 :48	153 (H, ncs)		111 - 146
		Erythrocytes (10^12/L)	Screening	09-12-2013/11 :48	5.19 (H, ncs)		4.02 - 5.08
		Eosinophils (10^9/L)	Screening	09-12-2013/11 :48	0.45 (H, ncs)		0.04 - 0.43
	Treatment Sequence 1	Erythrocytes (/HPF)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:39	12.00 (H, ncs)		0.00 - 3.00
		Erythrocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:39	250.00 (H, ncs)		0.00 - 5.00

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Bacteria	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:39	POSITIVE (H, ncs)		
		Leukocytes (/HPF)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:39	6.00 (H, ncs)		0.00 - 4.00
		Leukocytes (uL)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:39	25.00 (H, ncs)		0.00 - 9.00
		Protein (g/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:39	0.25 (H, ncs)		0.00 - 0.09
	Treatment Sequence 1	Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	21.2 (H, ncs)		5.0 - 21.0
		Hemoglobin (g/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	157 (H, ncs)		111 - 146
		Erythrocytes (10^12/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	5.39 (H, ncs)		4.02 - 5.08
		Direct Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	3.5 (H, ncs)		0.0 - 3.4
		Eosinophils (10^9/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	0.50 (H, ncs)		0.04 - 0.43
		Indirect Bilirubin (umol/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	17.7 (H, ncs)		1.6 - 17.6
		Monocytes (10^9/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	0.96 (H, ncs)		0.27 - 0.91

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Hematocrit (L/L)	Period 1,Day -1/ 24 H Predose	15-12-2013/ 8:41	0.46 (H, ncs)		0.35 - 0.44
	Treatment Sequence 1	Glucose (mmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:06	3.96 (L, ncs)		4.10 - 5.90
		Hemoglobin (g/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:06	148 (H, ncs)		111 - 146
		Erythrocytes (10^12/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:06	5.10 (H, ncs)		4.02 - 5.08
		Urea (mmol/L)	Period 2,Day -1/ 24 H Predose	20-01-2014/ 9:06	2.31 (L, ncs)		2.80 - 7.20
	Treatment Sequence 1	Erythrocytes (uL)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:25	10.00 (H, ncs)		0.00 - 5.00
	Treatment Sequence 1	Chloride (mmol/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	96.9 (L, ncs)		101.0 - 109.0
		Hemoglobin (g/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	149 (H, ncs)		111 - 146
		Sodium (mmol/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	134.2 (L, ncs)		136.0 - 146.0
		Erythrocytes (10^12/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	5.13 (H, ncs)		4.02 - 5.08
		Lymphocytes/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	14.4 (L, ncs)		17.8 - 48.5

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.4.1 Abnormal Laboratory Values (Safety Population)

Subject Number/ Random Number	Treatment Sequence	Lab Test (Unit)	Visit/ Timepoint	Date/Time of Measurement	Result (a,b)	Change From Baseline	Reference Range Low - High
		Monocytes (10^9/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	1.44 (H, ncs)		0.27 - 0.91
		Monocytes/Leukocytes (%)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	20.1 (H, ncs)		5.3 - 14.2
		Urea (mmol/L)	Period 3,Day -1/ 24 H Predose	25-02-2014/ 9:26	2.21 (L, ncs)		2.80 - 7.20
	Treatment Sequence 1	pH	Follow-Up	13-03-2014/11 :13	8.0 (H, ncs)	1.5	4.8 - 7.4
	Treatment Sequence 1	Urea (mmol/L)	Follow-Up	13-03-2014/11 :15	2.73 (L, ncs)	-0.81	2.80 - 7.20
	Treatment Sequence 2	Chloride (mmol/L)	Follow-Up	13-03-2014/ 8:11	100.2 (L, ncs)	-3	101.0 - 109.0
		Thyroxine (nmol/L)	Follow-Up	13-03-2014/ 8:11	57.6 (L, ncs)	-9.2	62.7 - 150.8
		Protein (mL/min/1.73m2)	Follow-Up	13-03-2014/ 8:11	65.6 (L, ncs)	-3.9	66.0 - 83.0
		Creatine Kinase (IU/L)	Follow-Up	13-03-2014/ 8:11	191.4 (H, ncs)	99.2	0.0 - 171.0

a: L = below lower limit of reference range, H = above upper limit of reference range; b: ncs = not clinically significant, cs = clinically significant
Baseline defined as Screening for Follow-Up results.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA.
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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15.3.5 Other Displays of Laboratory Data

Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Table 15.3.5.1.2 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Clinical Chemistry (Safety Population)

Levothyroxine
EMR 200125-002
Dosage Form Proportionality of Levothyroxine New Formulations (50 µg, 100 µg, and 200 µg Tablets) in Fasted State

Merck Serono
EMR 200125-002

Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Basophils (10^9/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	0.027 (0.018)		0.033 (0.023)		0.027 (0.013)	
		Median	0.020		0.030		0.030	
		Min; Max	0.01; 0.06		0.01; 0.08		0.01; 0.05	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	0.027 (0.019)		0.026 (0.016)		0.027 (0.014)	
		Median	0.020		0.020		0.020	
		Min; Max	0.01; 0.05		0.01; 0.06		0.01; 0.05	
	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	0.029 (0.012)		0.040 (0.028)		0.026 (0.013)	
		Median	0.020		0.030		0.020	
		Min; Max	0.02; 0.05		0.02; 0.09		0.01; 0.05	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Basophils (10^9/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	0.036 (0.021)		0.029 (0.023)		0.024 (0.008)		0.029 (0.018)	
		Median	0.030		0.020		0.030		0.030	
		Min; Max	0.02; 0.08		0.01; 0.08		0.01; 0.03		0.01; 0.08	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	0.030 (0.017)		0.030 (0.015)		0.020 (0.008)		0.027 (0.015)	
		Median	0.020		0.020		0.020		0.020	
		Min; Max	0.01; 0.06		0.02; 0.06		0.01; 0.03		0.01; 0.06	
	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	0.040 (0.022)		0.028 (0.008)		0.028 (0.015)		0.032 (0.017)	
		Median	0.040		0.030		0.025		0.030	
		Min; Max	0.02; 0.08		0.02; 0.04		0.01; 0.05		0.01; 0.09	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Populati on)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Basophils (10^9/L)	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	0.019 (0.009)		0.033 (0.029)		0.029 (0.020)	
		Median	0.020		0.025		0.020	
		Min; Max	0.01; 0.03		0.01; 0.09		0.01; 0.07	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	0.029 (0.012)	0.001 (0.012)	0.026 (0.011)	-0.007 (0.016)	0.033 (0.011)	0.006 (0.005)
		Median	0.020	0.010	0.030	0.000	0.030	0.010
		Min; Max	0.02; 0.05	-0.02; 0.01	0.01; 0.04	-0.04; 0.01	0.02; 0.05	0.00; 0.01
Basophils/ Leukocytes (%)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	0.50 (0.258)		0.61 (0.329)		0.51 (0.234)	
		Median	0.50		0.60		0.50	
		Min; Max	0.2; 0.9		0.2; 1.2		0.2; 0.9	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Populati on)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Basophils (10^9/L)	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	0.038 (0.026)		0.025 (0.014)		0.035 (0.021)		0.029 (0.020)	
		Median	0.030		0.020		0.040		0.020	
		Min; Max	0.02; 0.09		0.01; 0.05		0.01; 0.06		0.01; 0.09	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	0.044 (0.034)	0.009 (0.017)	0.031 (0.015)	0.003 (0.011)	0.023 (0.011)	-0.001 (0.012)	0.031 (0.018)	0.002 (0.013)
		Median	0.030	0.000	0.030	0.010	0.020	0.000	0.030	0.000
		Min; Max	0.02; 0.12	-0.01; 0.04	0.02; 0.06	-0.02; 0.01	0.01; 0.04	-0.02; 0.02	0.01; 0.12	-0.04; 0.04
Basophils/ Leukocytes (%)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	0.69 (0.564)		0.56 (0.486)		0.49 (0.121)		0.56 (0.349)	
		Median	0.40		0.50		0.50		0.50	
		Min; Max	0.3; 1.8		0.2; 1.6		0.3; 0.7		0.2; 1.8	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Populati on)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Basophils/ Leukocytes (%)	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	0.49 (0.318)		0.47 (0.221)		0.49 (0.273)	
		Median	0.40		0.40		0.40	
		Min; Max	0.2; 1.0		0.2; 0.9		0.1; 0.9	
	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	0.50 (0.208)		0.75 (0.428)		0.54 (0.294)	
		Median	0.50		0.60		0.40	
		Min; Max	0.3; 0.9		0.4; 1.5		0.2; 1.0	
	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	0.31 (0.146)		0.58 (0.337)		0.61 (0.438)	
		Median	0.30		0.55		0.50	
		Min; Max	0.2; 0.6		0.2; 1.2		0.2; 1.5	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Basophils/ Leukocytes (%)	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	0.47 (0.198)		0.57 (0.368)		0.39 (0.186)		0.48 (0.258)	
		Median	0.50		0.50		0.50		0.40	
		Min; Max	0.2; 0.8		0.3; 1.3		0.1; 0.6		0.1; 1.3	
	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	0.68 (0.417)		0.47 (0.163)		0.65 (0.383)		0.59 (0.321)	
		Median	0.55		0.45		0.60		0.50	
		Min; Max	0.4; 1.5		0.3; 0.7		0.2; 1.3		0.2; 1.5	
	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	0.70 (0.460)		0.43 (0.234)		0.67 (0.437)		0.55 (0.362)	
		Median	0.55		0.45		0.65		0.50	
		Min; Max	0.3; 1.6		0.1; 0.8		0.2; 1.3		0.1; 1.6	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Populati on)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Treatment Sequence 1 (N=7) Change	Treatment Sequence 2 (N=7) Observed	Treatment Sequence 2 (N=7) Change	Treatment Sequence 3 (N=7) Observed	Treatment Sequence 3 (N=7) Change
Basophils/ Leukocytes (%)	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	0.56 (0.251)	0.06 (0.230)	0.49 (0.219)	-0.13 (0.335)	0.60 (0.200)	0.09 (0.090)
		Median	0.40	0.20	0.60	-0.10	0.50	0.10
		Min; Max	0.3; 1.0	-0.3; 0.3	0.2; 0.7	-0.8; 0.3	0.4; 1.0	0.0; 0.2
Eosinophils (10^9/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	0.166 (0.130)		0.179 (0.156)		0.183 (0.112)	
		Median	0.130		0.100		0.200	
		Min; Max	0.07; 0.45		0.08; 0.50		0.05; 0.33	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	0.176 (0.150)		0.223 (0.187)		0.153 (0.092)	
		Median	0.130		0.170		0.120	
		Min; Max	0.07; 0.50		0.12; 0.64		0.06; 0.29	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Basophils/ Leukocytes (%)	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	0.77 (0.515)	0.09 (0.204)	0.57 (0.287)	0.01 (0.285)	0.46 (0.237)	-0.03 (0.198)	0.57 (0.303)	0.01 (0.234)
		Median	0.60	0.10	0.60	0.10	0.50	0.00	0.50	0.05
		Min; Max	0.4; 1.9	-0.3; 0.4	0.2; 1.0	-0.6; 0.2	0.2; 0.8	-0.3; 0.3	0.2; 1.9	-0.8; 0.4
Eosinophils (10^9/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	0.170 (0.075)		0.147 (0.093)		0.146 (0.072)		0.165 (0.105)	
		Median	0.160		0.120		0.110		0.125	
		Min; Max	0.07; 0.29		0.05; 0.31		0.08; 0.27		0.05; 0.50	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	0.187 (0.084)		0.209 (0.139)		0.184 (0.091)		0.189 (0.123)	
		Median	0.170		0.160		0.220		0.165	
		Min; Max	0.10; 0.31		0.12; 0.51		0.06; 0.31		0.06; 0.64	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Treatment Sequence 1 (N=7) Change	Treatment Sequence 2 (N=7) Observed	Treatment Sequence 2 (N=7) Change	Treatment Sequence 3 (N=7) Observed	Treatment Sequence 3 (N=7) Change
Eosinophils (10^9/L)	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	0.193 (0.129)		0.237 (0.155)		0.173 (0.088)	
		Median	0.150		0.190		0.120	
		Min; Max	0.07; 0.42		0.10; 0.54		0.08; 0.29	
	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	0.123 (0.063)		0.190 (0.150)		0.157 (0.099)	
		Median	0.140		0.145		0.140	
		Min; Max	0.05; 0.21		0.08; 0.48		0.06; 0.33	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	0.159 (0.080)	-0.007 (0.066)	0.217 (0.106)	0.039 (0.085)	0.199 (0.128)	0.016 (0.075)
		Median	0.140	0.020	0.220	0.030	0.160	0.040
		Min; Max	0.08; 0.31	-0.14; 0.05	0.12; 0.43	-0.07; 0.16	0.05; 0.38	-0.12; 0.11

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Populati on)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Eosinophil s (10^9/L)	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	0.233 (0.152)		0.245 (0.161)		0.142 (0.068)		0.203 (0.126)	
		Median	0.210		0.180		0.120		0.165	
		Min; Max	0.08; 0.52		0.12; 0.53		0.09; 0.27		0.07; 0.54	
	Period 3/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	0.230 (0.165)		0.322 (0.186)		0.172 (0.115)		0.196 (0.140)	
		Median	0.160		0.315		0.145		0.145	
		Min; Max	0.11; 0.55		0.13; 0.54		0.08; 0.39		0.05; 0.55	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
		Mean (SD)	0.281 (0.295)	0.111 (0.237)	0.227 (0.142)	0.080 (0.095)	0.146 (0.080)	0.000 (0.069)	0.205 (0.154)	0.040 (0.121)
		Median	0.210	0.020	0.180	0.070	0.120	0.020	0.160	0.030
		Min; Max	0.07; 0.91	-0.05; 0.62	0.10; 0.51	-0.02; 0.27	0.07; 0.31	-0.10; 0.09	0.05; 0.91	-0.14; 0.62

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Eosinophils/Leukocytes (%)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	3.03 (1.735)		3.63 (3.460)		3.36 (2.022)	
		Median	2.70		1.90		3.70	
		Min; Max	1.3; 6.6		1.4; 10.9		0.9; 5.6	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	3.01 (1.933)		4.11 (3.246)		2.80 (1.883)	
		Median	2.60		3.00		2.20	
		Min; Max	1.6; 7.1		2.3; 11.4		0.5; 5.3	
	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	3.36 (2.248)		4.53 (3.105)		3.56 (2.124)	
		Median	2.30		3.35		2.40	
		Min; Max	1.7; 7.5		2.6; 10.7		1.6; 6.1	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 4 (N=7) Observed	Change	Treatment Sequence 5 (N=7) Observed	Change	Treatment Sequence 6 (N=7) Observed	Change	Total (N=42) Observed	Change
Eosinophil s/Leukocytes (%)	Screening	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	3.04 (1.659)		2.70 (1.840)		3.13 (2.072)		3.15 (2.098)	
		Median	2.80		2.40		2.30		2.55	
		Min; Max	1.7; 6.5		1.0; 6.6		1.2; 7.2		0.9; 10.9	
	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
		Mean (SD)	3.00 (1.003)		3.51 (1.555)		3.71 (2.081)		3.36 (1.990)	
		Median	2.90		3.00		3.60		2.95	
		Min; Max	1.7; 4.3		2.3; 6.8		1.0; 7.0		0.5; 11.4	
	Period 2/ (Day -1)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
		Mean (SD)	4.02 (2.902)		3.75 (1.781)		3.22 (1.809)		3.72 (2.248)	
		Median	3.15		2.95		2.70		2.75	
		Min; Max	1.8; 9.5		2.3; 6.6		1.8; 6.7		1.6; 10.7	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Populati on)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Eosinophil s/Leukocyt es (%)	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	1.97 (1.013)		3.85 (3.102)		3.26 (2.081)	
		Median	2.00		2.90		2.20	
		Min; Max	0.7; 3.6		1.1; 9.8		1.1; 6.3	
	Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)
		Mean (SD)	2.96 (1.408)	-0.07 (1.179)	3.94 (2.015)	0.31 (1.674)	3.60 (2.189)	0.24 (1.318)
		Median	2.20	0.40	3.10	0.80	3.10	0.60
		Min; Max	1.7; 5.3	-1.6; 1.3	2.2; 8.0	-2.9; 2.6	0.9; 6.1	-2.4; 1.7
Erythrocyt es (10^12/L)	Screening	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	4.831 (0.309)		4.693 (0.407)		4.644 (0.581)	
		Median	4.920		4.740		4.570	
		Min; Max	4.23; 5.19		4.06; 5.38		3.99; 5.55	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Population)

		Treatment Sequence 4 (N=7)		Treatment Sequence 5 (N=7)		Treatment Sequence 6 (N=7)		Total (N=42)	
Laboratory Visit/ Test (Unit) Timepoint	Statistics	Observed	Change	Observed	Change	Observed	Change	Observed	Change
Eosinophil Period 3/ s/Leukocyt (Day -1) es (%)	n (missing)	6 (0)		6 (0)		6 (0)		38 (0)	
	Mean (SD)	4.23 (3.040)		5.52 (4.346)		3.17 (1.626)		3.61 (2.748)	
	Median	3.25		4.90		2.75		2.70	
	Min; Max	1.7; 10.0		1.4; 13.8		1.6; 5.9		0.7; 13.8	
Follow-Up	n (missing)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	7 (0)	42 (0)	42 (0)
	Mean (SD)	4.80 (4.635)	1.76 (3.003)	4.20 (3.042)	1.50 (1.513)	3.04 (1.984)	-0.09 (1.113)	3.76 (2.662)	0.61 (1.806)
	Median	4.10	0.80	3.00	1.50	2.40	0.10	2.95	0.65
	Min; Max	1.1; 14.7	-0.6; 8.2	1.7; 10.7	-0.7; 4.1	1.7; 7.4	-1.5; 1.7	0.9; 14.7	-2.9; 8.2
Erythrocyt Screening es (10^12/L)	n (missing)	7 (0)		7 (0)		7 (0)		42 (0)	
	Mean (SD)	4.684 (0.630)		4.643 (0.379)		5.001 (0.458)		4.750 (0.463)	
	Median	4.300		4.610		5.090		4.725	
	Min; Max	4.11; 5.61		4.07; 5.36		4.36; 5.59		3.99; 5.61	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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Table 15.3.5.1.1 Summary and Change from Baseline of Laboratory Data by Treatment and Time Point: Hematology (Safety Populati on)

Laboratory Test (Unit)	Visit/ Timepoint	Statistics	Treatment Sequence 1 (N=7) Observed	Change	Treatment Sequence 2 (N=7) Observed	Change	Treatment Sequence 3 (N=7) Observed	Change
Erythrocytes (10^12/L)	Period 1/ (Day -1)	n (missing)	7 (0)		7 (0)		7 (0)	
		Mean (SD)	4.887 (0.307)		4.733 (0.324)		4.637 (0.596)	
		Median	4.840		4.760		4.650	
		Min; Max	4.49; 5.39		4.35; 5.23		3.85; 5.32	
	Period 2/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	4.954 (0.255)		4.790 (0.402)		4.626 (0.545)	
		Median	5.030		4.780		4.470	
		Min; Max	4.64; 5.27		4.26; 5.40		3.89; 5.44	
	Period 3/ (Day -1)	n (missing)	7 (0)		6 (0)		7 (0)	
		Mean (SD)	4.929 (0.308)		4.782 (0.378)		4.587 (0.534)	
		Median	4.940		4.755		4.370	
		Min; Max	4.54; 5.36		4.21; 5.39		3.95; 5.19	

Baseline defined as Screening for Follow-Up results.
Max: Maximum Value; Min: Minimum Value; N: The number of subjects dosed with each treatment, or the number of subjects in the safety population for the total summary; n: Number of subjects in specific laboratory tests.
Treatment Sequence 1:ABC; Treatment Sequence 2: BCA; Treatment Sequence 3: CAB; Treatment Sequence 4: ACB; Treatment Sequence 5: BAC; Treatment Sequence 6: CBA;
Treatment A: 12 tablets of 50 µg of levothyroxine; Treatment B: 6 tablets of 100 µg of levothyroxine
Treatment C: 3 tablets of 200 µg of levothyroxine

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