

25 February 2016

Rennes clinical trial: information on studies carried out on animals

Before testing new medicinal products on humans, it is essential to carry out studies on animals, called pre-clinical trials. This involves conducting pharmacology, pharmacokinetic and toxicity studies.

These studies aim to specify the mechanism of action of the medicinal product, assess its activity, its evolution in the organism, and to establish toxic dose levels. As part of these toxicology studies, very high doses are administered in order to determine the maximum tolerated doses that could be lethal in animals.

As part of the investigations relating to the Rennes clinical trial, ANSM (French National Agency for Medicines and Health Products Safety) provided the CSST (temporary specialised scientific committee composed of French and independent international experts) with all of the data available on the studies carried out on animals with BIA 10-2474, including those in which dogs died. The CSST concluded that, on the basis of a detailed analysis of the toxicological data available, the results of the studies carried out on animals met the necessary prerequisites and, as a result, allowed testing on humans to begin.

Further data was requested from the promoter (Bial Laboratory) by the group of experts in order to provide more detail and substantiate this analysis. The CSST is continuing its work and will submit its findings at the end of March.

International recommendations¹ govern these studies which must be carried out on animals before being administered to humans. Similarly, ethical regulations, decreed at European level, apply to these experiments².

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¹ ICH Topic M3 (R2) – Non-Clinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorisation for Pharmaceuticals.

Note for guidance on non clinical safety studies for the conduct of human clinical trials and marketing authorisation for pharmaceuticals. (CPMP/ICH/286/95) – July 2008

² Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes.