Agence nationale de sécurité du médicament et des produits de santé

Information Bulletin

BIAL Laboratory Clinical Trial BIA-102474-101: Publication of the Clinical Protocol

The French National Agency for Medicines and Health Products Safety (ANSM) published BIAL laboratory's clinical trial BIA-102474-101 protocol.

This protocol was authorized by ANSM on June 26, 2015 and approved by the Ethics Committee (Comité de protection des personnes -CPP-) on July 3, 2015. It describes the conditions and supervision of the trial conducted by the Biotrial research centre.

However, BIAL denied ANSM's request to publish two other documents, on the pretext of trade secrets protection, covered by Article L311-6 of the "relations between the public and administration" French Code. These documents are the Investigational Medicinal Product Dossier which provides pharmaceutical information and the Investigator's Brochure which provides information on animal studies conducted with the drug being tested in the trial.

The laboratory submitted its application file for clinical trial authorization to ANSM on April 30, 2015. On June 26, 2015, after 2 months of scientific investigation, ANSM authorized trial BIA-102474-101/1BIAL35 entitled "Double-blind, randomized, placebo-controlled study, combining ascending single dose, multiple ascending dose, and food interaction studies in order to evaluate the safety, tolerability, pharmacokinetic and pharmacodynamic profiles of BIA 10-2474 in healthy volunteers."

The first volunteers were accepted in July 2015.

The protocol approved by ANSM on June 2015 was subjected to a modification request in October. The only change was the investigator's name, approved by the CPP on November 4, 2015.

In its evaluation ANSM, took into account the European recommendation on first-in-man administration. This recommendation can be found on ANSM website under the following link:

http://ansm.sante.fr/content/download/1491/14525/version/4/file/reco-essais-clinique-premier-administration-homme.pdf

In addition, ANSM has decided to establish a temporary Specialized Scientific Committee (CSST) composed of pharmacologists, toxicologists and neurologists.

CSST's mission is to analyse all existing data concerning the pharmacological class of FAAH (Fatty Acid Amide Hydrolase) inhibitors used in this test.

The decision to create this committee was posted on ANSM website on January 21, 2016 (http ://ansm.sante.fr/content/download/84649/1068859/version/1/file/CSST-Decision-2016-17-21-FAAH.pdf).

Further reading

Clinical trial protocol (July 2015)