

**The occurrence of serious adverse events, resulting in the hospitalisation of six patients and leaving one of them brain-dead, led to the premature discontinuation of a BIAL laboratory clinical trial**

On 14 January 2016, the French National Agency for Medicine and Health Product Safety (ANSM) was informed of serious adverse events observed in healthy volunteers taking part in a clinical trial. These events led to the hospitalisation of six volunteers, including one who is brain-dead and in intensive care. This is an exceptional situation. The Phase I clinical trial, conducted by the BIOTRIAL company on behalf of BIAL laboratory, was immediately suspended.

In addition, all trial volunteers are asked to call 02 99 28 24 47 for additional testing.

The clinical trial was authorised by ANSM on 26 June of last year and approved by the Ethics Committee (Comité de Protection des Personnes) West VI, located in Brest, on 3 July 2015. The trial was conducted exclusively at BIOTRIAL'S clinical centre based in Rennes. The molecule under study, with potential analgesic properties, acts on an endogenous neurotransmitter. The trial consisted of two initial phases during which no serious adverse events were reported. The third phase was intended for administration in multiple doses. The emergence of serious adverse events took place after six volunteers were administered the highest tested dose.

BIAL, the laboratory sponsor, informed ANSM and BIOTRIAL, the company responsible for the trial's implementation, of the study's interruption.

Today, ANSM commissioned an inspection of the BIOTRIAL company.

A clinical trial is an organised biomedical research study, practised on human participants, for the purpose of advancing biological and medical knowledge. Depending on the circumstances, clinical drug trials have the goal of establishing or verifying certain kinds of data—**pharmacokinetic** (method of absorption, distribution, metabolism and excretion of the drug), **pharmacodynamic** (mechanism of drug action in particular) and **therapeutic** (effectiveness and tolerance)—pertaining to a new drug or a new way of using a known treatment in order to ensure its safety or effectiveness.

A clinical trial may be conducted using either sick or healthy volunteers.

Phase I clinical trials are most often conducted on healthy volunteers and are aimed at evaluating tolerance to the tested substance.

In order to begin, the trial must first obtain approval from the Ethics Committee (C.P.P.) and authorisation from the French National Agency for Medicine and Health Product Safety (ANSM).

*Further reading*

[http://ansm.sante.fr/Activites/Essais-cliniques/Les-essais-cliniques/\(offset\)/0](http://ansm.sante.fr/Activites/Essais-cliniques/Les-essais-cliniques/(offset)/0)