

Gilles DULUC

Directeur de la Recherche Clinique
et de l'Innovation

Talence, le 13/05/2025

Jeanne PATARD

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Département Promotion Interne**Anne GIMBERT**

Responsable
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Object : Interventional Clinical Trial's results posting to the European Clinical Trial register (EudraCT) of the European Medicines Agency (EMA).

In accordance of Directive 2001/20/CE

Study Title : HIPPIE : The role of dexchlorpheniramine (Polaramine®) to prevent hemodynamic instability after separation from cardiopulmonary bypass during cardiac surgery.

EudraCT Nbr : 2015-000505-39

Sponsor Nbr : CHUBX2014/13 / **ANSM Nbr :** 150160A-21

Transitioned study to the Regulation (EU) 536/2014 : no

Status of the study : prematurely ended study

The study HIPPIE has been prematurely ended because of a low recruitment rate. The budget didn't allow the trial to continue, and the principal investigator and associate investigators had left the Bordeaux University Hospital during the trial. The medical and research staff was involved in other research projects.

Finally, the number of patients included, compared with the number expected in the trial was under expectations (n= 18 instead of n= 48) ; continuing patient's recruitment would not have enabled us to achieve the number of subjects needed to answer the research question.

This early termination of the study made it impossible to meet the trial's main objective, and to assess the benefit/risk ratio of the experimental drug in the

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pathology studied. An end-of-study meeting was held and concluded that the trial couldn't be valorized.

For the Head of the University Hospital of Bordeaux
and by delegation,
The Director of the Clinical research and Innovation

Gilles DULUC

by delegation

Anne GIMBERT
Responsable Promotion Interne
Direction de la Recherche Clinique et de l'Innovation