CHU BDX CENTRE HOSPITALIER UNIVERSITAIRE BORDEAUX

Direction de la Recherche Clinique et de l'Innovation
Promotion Interne

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Talence, le 12/05/2025

Object : Interventional Clinical Trial's results posting to the European Clinical Trial register (EudraCT) of the European Medicines Agency (EMA).
In accordance of the Directive 2001/20/CE
Study Title : LAPAINBLAD : Pilot study of Lapatinib (Tyverb®) in neoadjuvant treatment for patients with locally bladder carcinoma before cystectomy
EudraCT Nbr : 2009-012714-49
Sponsor Nbr : CHUBX2009/04 / **Afssaps Nbr** : A90997-51
Transitioned study to the Regulation (EU) 536/2014 : no
Status of the study : prematuraly ended study

The participating centers associated with Bordeaux University Hospital at the start of the study could not be involved:

- organizational problems with the center in the UK,
- change of location of the principal investigator in France, , in 3 differents sites since the start of the study

Amendment no. 2 of 08/02/2012, concerning in particular the extension of the inclusion period and the addition of 2 new sites, required a response to a request for additional information from the ethic committee and received a favourable opinion on 27/06/2012. However, the opening of these new sites was no longer compatible with the study schedule, especially as ANSM authorization had yet to be obtained for this amendment n°2 and for the distribution of the drug in these 2 sites.

As a result, the coordinating investigator decided to terminate the study early, since it had become impossible to keep up the pace of enrolment, and therefore to recruit the planned number of patients, even though Bordeaux University Hospital was within the recruitment range.

The study was only able to include 3 patients out of the 15 planned, but only at the Bordeaux University Hospital.
The 3 patients included in 2011 were able to complete the entire study, including initial lapatinib treatment with maximum grade 1 toxicity, radical cystectomy on schedule, without delay or added difficulty, and full recovery from lapatinib-induced side effects at the end-of-study visit.

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