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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 : KerNéO : Subconjunctival injection of ranibizumab (Lucentis®) for ocular surface neovascularization (OSN) : KerNéO study
EudraCT Nbr : 2010-020683-38
Sponsor Nbr : CHUBX2009/30 / **Afssaps Nbr** : A100590-77
Transitioned study to the Regulation (EU) 536/2014 : no
Status of the study : prematuraly ended study

The initial protocol planned a large number of visits for each patient (12 visits). In practice, it appeared difficult for the ophtalmology department to schedule appointments for each of these visits, given that a special box had to be reserved for taking photographs, that the ophthalmology department's activity was dense, and that only one investigator could ensure the recruitment and follow-up of participants within the framework of the protocol (overlapping appointments with a single ophthalmologist impossible).
In view of these factors, it seemed appropriate to submit an amendment to the competent authorities (CPP and ANSM), validated by the project's stakeholders (Novartis, principal investigator, etc.); this amendment n°1 aimed to simplify the research schedule (reduction in the number of follow-up visits for participants), and modified the primary endpoint (based on treatment tolerance during the 3 injections at D0/D30 and D60).
The ANSM authorized this amendment n°1 on August 30, 2012; however, the CPP SOOM3 issued an unfavorable opinion on the implementation of this amendment, arguing that "the reduction in the number of follow-up visits for the only purpose of increasing recruitment is

not a sufficient justification for the substantial modification of the efficacy and tolerance objective".

This unfavourable opinion therefore calls into question the feasibility of the research. The study has consequently been stopped early for unfeasibility.

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

Gilles DULUC