Newsletter N° 6 – JANUARY 2021

TREOCAPA
a c4c study

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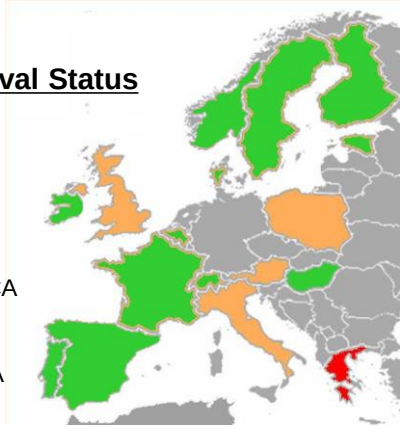
Inserm

Prophylactic TREatment Of the duCtus Arteriosus in Preterm infants by Acetaminophen

Dear Investigators, dear National Hubs,
First of all, we wish you **a Happy New Year 2021!**
We look forward to a year full of achievements for the Treocapa study thanks to your collaboration and investment!

Regulatory Approval Status



Both NCA/EC approvals received

Pending either NCA or EC approval

Pending both NCA and EC approvals

Site Opening Status:

11 sites are currently open for recruitment in France, Switzerland, Finland and Estonia and at least 9 additional sites will open by the end of February 2021.

Inclusions:

Phase II : 8 inclusions / Target : 30 patients
Phase III : 6 inclusions / Target : 794 patients

Phase II :
Dose finding phase for 23-26 GA

2 cohorts of 3 patients have been completed and as part of the continual reassessment method, two interim statistical analysis were performed. Results of both analysis indicated that dose level 1 should be maintained to the next cohort
(dose level 1 = 20 mg/kg loading dose then 7,5mg/kg/6 hours).

Treocapa Follow-Up amendment

The steering committee proposed an amendment to allow a follow-up. A protocol has been developed with a primary safety outcome that consists of evaluating survival without moderate or severe neurodevelopmental disability at 2 years corrected age.

A follow-up protocol proposal along with a funding request was submitted to c4c on Dec. 29, 2020. We expect to receive feedback from the Trial Commissioning Committee in the coming weeks.

Treocapa Steering committee

Our third SC meeting was held on December 16 and 17, 2020 by web-conference. During this meeting, the creation of workgroups was discussed.
The aim of these workgroups is to maintain a collaborative work among SC members and support the development of ancillary studies.
SC members agreed on the setting up of 5 workgroups:

1	Pain, comfort and parent involvement	Leads: Ricardo Carbajal, Pierre Khun, Corinne Alberti
2	Neurology	Leads: Olivier Baud, Gorm Greisen, Mikko Hallman
3	Variations of practices	Leads : Pierre-Yves Ancel, Neil Marlow
4	Follow-up	Leads: Andrei Morgan, Pierre-Yves Ancel and Neil Marlow Additional members: Gorm Greisen, Mikko Hallman, Eugene Dempsey
5	Pharmacology	Leads: Naim Bouazza, Jean-Marc Treluyer, Mikko Hallman

TREOCAPA is a study co-developed with parents and their European representatives.

EFCNI
european foundation for the care of newborn infants

This study is funded by the c4c project. Find out more here: https://conect4children.org/

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