Newsletter N° 18 – June 2023

TREOCAPA
a c4c study

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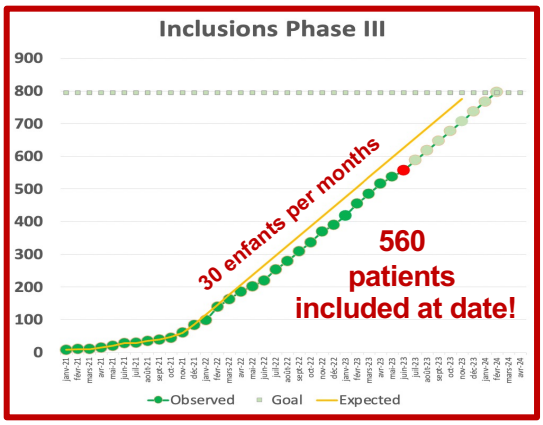
Prophylactic TREatment Of the duCtus Arteriosus in Preterm infants by Acetaminophen

Dear Investigators, Dear All,
We reached **560**/794 patients at the end of June!
But the inclusion rate in May and June was lower than expected. Let's try to maintain a rate of 30 inclusions per month over the summer !
Thank you all for your involvement.



WELCOME to ITALIA !

With the opening of the 45th neonatal intensive care unit, in Italy. So, 15 countries are now participating in the TREOCAPA study.

TREOCAPA'S LATEST NEWS :

1. Phase II results paper

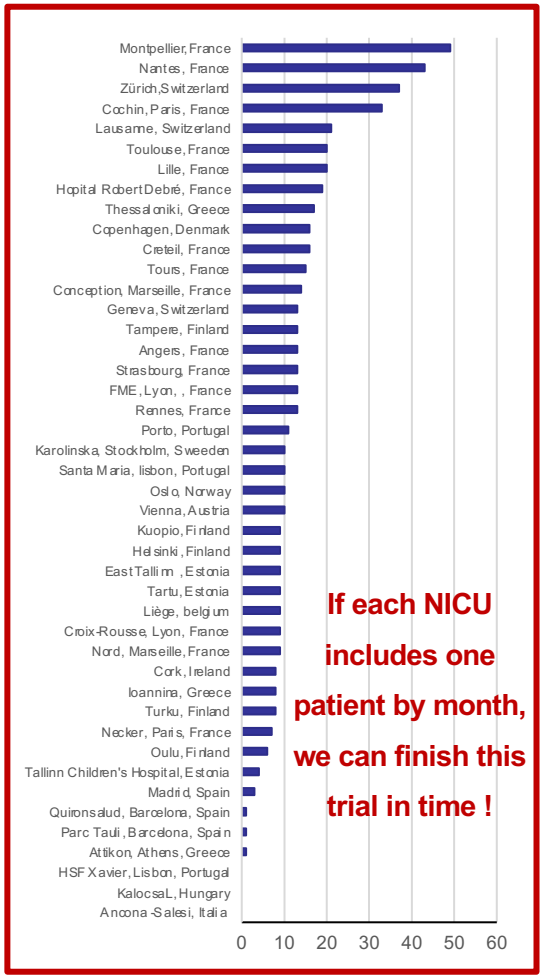
The Treocapa phase II paper was submitted and is still under review ! We will keep you updated once published.

2. The mid-term Interim Analysis

We would like to thank you sincerely for your work in filling in the eCRF, in particular for the visit 3 ! The mid-term interim analysis will be performed and will be presented to the DSMB, made up of Prs MacNamara (USA), Soll (USA), Barrington (Canada), Durier (France), Kaguelidou(France), in a closed session on July 13, 2023. The recommendation of the DSMB will be forwarded to the Steering Committee after for its decision on the continuation of the trial.

3. Reminder

The investigator in charge of the premature baby (who performed the study inclusion) is responsible for the quality of the data recorded in the eCRF, in particular the data for visit 3, which are used to define the primary outcome. This is particularly important if the premature baby is transferred to a secondary center. The investigator must contact the peripheral center to validate visit 3 data.



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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