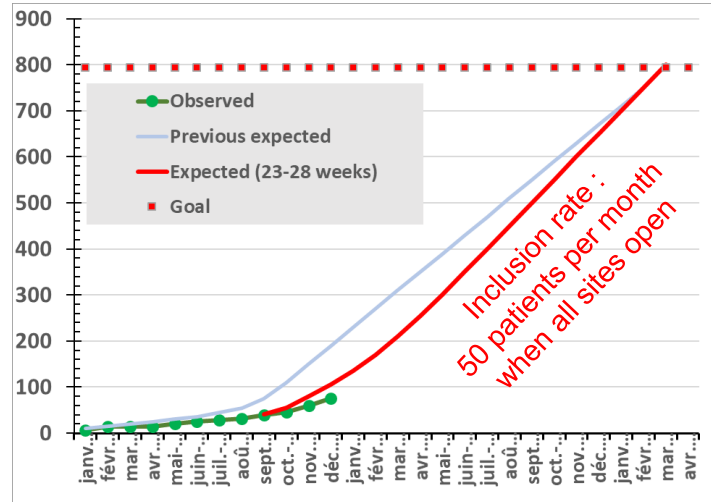


Prophylactic **TRE**atment **O**f the du**C**tus **A**rteriosus in **P**reterm infants by **A**cetaminophen

Dear Investigators, Dear all,

With **30 sites open** to recruitment in 9 countries, patient inclusions in the **TREOCAPA Phase III study** are progressing well with **76 patients** included to date.

Recruitment is now competitive !
 Since Dec. 1st, we observed **1 inclusion per day**.
 Thanks to all investigators for their involvement in TREOCAPA



TREOCAPA Phase II study – Feedback from Naim Bouazza, methodologist and statistician:

“A total of 31 preterms were enrolled in the phase II study. As planned, the distribution of gestational ages was well-balanced (12 patients in 23-24 W, 7 patients in 25 W and 12 patients in 26 W GA). This study provides, for the first time, very rich data regarding efficacy of acetaminophen to close the ductus in these vulnerable patients. Valuable and very important data regarding longitudinal cardiac echographies during the first week of life have been recorded.”

“Furthermore, this is the first study evaluating high loading and maintenance doses in extremely premature infants providing very useful safety data. Pharmacokinetic blood samples were also collected. Acetaminophen plasma levels as well as its metabolites have been measured and will provide useful insight in the knowledge of acetaminophen metabolism and elimination in the extremely preterm infant.”

Warning!
Inclusions will be suspended from January 17th to 21th for eCRF software update

Unblinding Process Reminder

Only if unblinding is absolutely necessary, the PI must call the Poison control Center - Hôpital Fernand Widal at **+33 1 40 05 48 48**

Unblinding request must be as clear as possible indicating that the medical management of a newborn is at stake.

If needed, help is possible at **+33 6 25 92 58 45**



With Best Wishes From The TREOCAPA Study Team

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

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