TREOCAPA
a c4c study

PARENT INFORMATION SUMMARY

TREOCAPA: an international trial conducted in more than 60 centres of 17 European countries. TREOCAPA tries to find out whether the preventive use of paracetamol in preterm infants during the first five days of life is safe and effective to close the ductus arteriosus blood vessel and reduces the risk of prematurity associated complications.

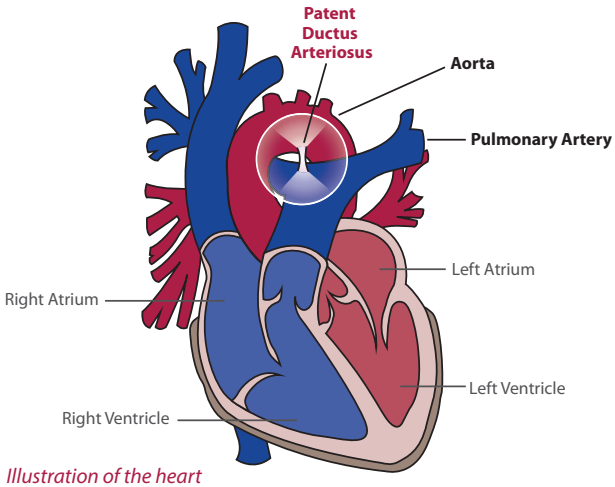


Illustration of the heart showing the location of the ductus arteriosus blood vessel

The Ductus Arteriosus is present in all babies before birth and normally closes in the days following birth. However, in about 60% of preterm born babies (born before the completion of 37 weeks of pregnancy), this blood vessel remains open. This is most often the case in the more premature ones. If this vessel does not close, babies often experience more complications of prematurity with the lungs, brain, and gut than babies, in which this vessel does close.

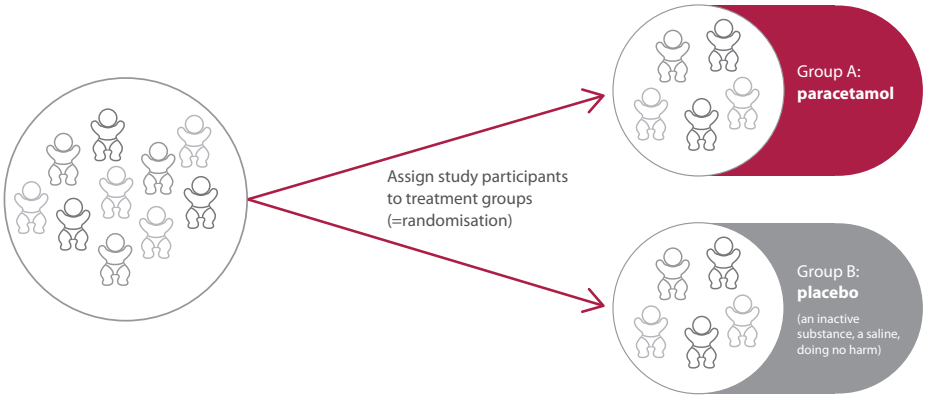
Certain drugs (indomethacin or ibuprofen) that can be used to close the ductus arteriosus have many adverse effects. Recently, it has been shown that prophylactic (preventative) use of paracetamol, a drug with far fewer side effects, can also close the ductus arteriosus. This drug is widely used in neonatology (the care of newborns, especially preterm and ill babies) against pain.

AIM OF THE STUDY

This trial will investigate whether the prophylactic use of paracetamol in preterm babies during their first five days of life is safe and effective in reducing risk of death or severe complications of prematurity, like brain bleedings, pulmonary lesions or eye problems, by preventing a persistent ductus arteriosus. Additionally, the influence of paracetamol on pain and on the use of pain killers as well as long-term effects of paracetamol are currently being investigated. The trial will be conducted in more than 60 centres of 17 European countries. A total of 794 preterm babies will be included over a period of 28 months. The trial will last 38 months in total.

ALLOCATION OF THE PARTICIPANTS IN THE STUDY GROUP

In this study **two different treatments** will be compared to each other.
Therefore, all patients will be allocated to one of two groups.



A computer will be used to assign study participants into treatment groups by chance. This is called **randomisation** and can be compared to drawing lots. Your baby has a 1 in 2 chance of being placed in either group. Neither you, nor the study team will know which treatment your baby receives (this is called double-blind). This is to make sure the results of each group being studied are handled in the same way.

STUDY PROCEDURE

Study enrolment and the first administration of either paracetamol or placebo must be given intravenously within the first 12 hours after birth. During the first 5 days of life, further intravenous infusions will follow at 6-hourly intervals for 15 minutes each (total of 20 doses). For the safety of your baby, after the 1st and after 10th injection of paracetamol, a supplementary blood sample (0.1 to 0.3mL, depending on the local practices) will be taken during routine care to measure the level of markers to determine how well the liver is working.

In addition to the intravenous infusions (placing fluids into the bloodstream through a vein), three time points are particularly important during the TREOCAPA trial: on the 7th day of life, an ultrasound of the heart will be performed. On the 7th and on the 28th day of life and what would have been week 36 of pregnancy (postmenstrual age) or at discharge, medical data will be collected.

BENEFITS & POTENTIAL RISKS

BENEFITS OF TAKING PART IN THE STUDY	The very controlled environment of a clinical study leads to additional, more intensive check-ups for the babies. In addition, preventive strategies for the ductus arteriosus may be improved and may help other babies in the future.
POTENTIAL SIDE EFFECTS	Paracetamol has been approved by many European health authorities for use in preterm babies. Very rarely, paracetamol may cause harmful side effects, just like any other medication. No side effects have been observed in preterm infants with the specific doses used in the study.
POTENTIAL RISKS / POSSIBLE PAINS	In the course of the study, your baby will receive several infusions with Paracetamol through a central venous line that is already set up for the routine care of your baby. The set-up of the central venous line may cause a slight pain at the site of puncture.

OTHER TREATMENT OPTIONS

The ductus arteriosus may close spontaneously without any intervention. Common treatment options for a patent ductus arteriosus would include intravenous medications such as indomethacin or ibuprofen or closure by cardiac surgery. The investigator will advise you on the other treatment options available.

LEAVING THE STUDY

Your baby will only be included in the study if you agree with this and have signed the informed consent form. At any time, you can change your mind and your baby can leave the study. If you no longer want your baby to participate in the study, please tell your study doctor. Your choice will not change the quality of care your baby receives while in the hospital and after discharge.

DATA PROTECTION

All legal regulations of data protection are observed and all parties involved are subject to the obligation of secrecy. The personal and medical data and samples are used and protected in encrypted form (with birth date but without name). The data and samples will only be used for other research projects if you give your consent.

Further and more detailed information on the study is available in the Parent's Informed Consent Form and will be discussed thoroughly with you by the doctor in charge.

No financial compensation will be paid to study participants.

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