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.

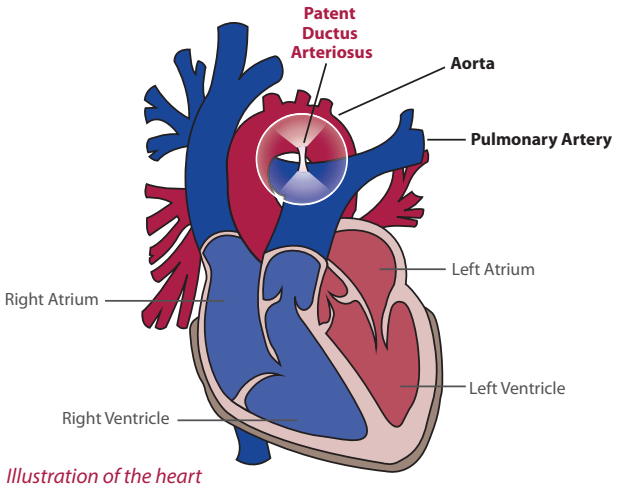


Illustration of the heart showing the location of the ductus arteriosus blood vessel

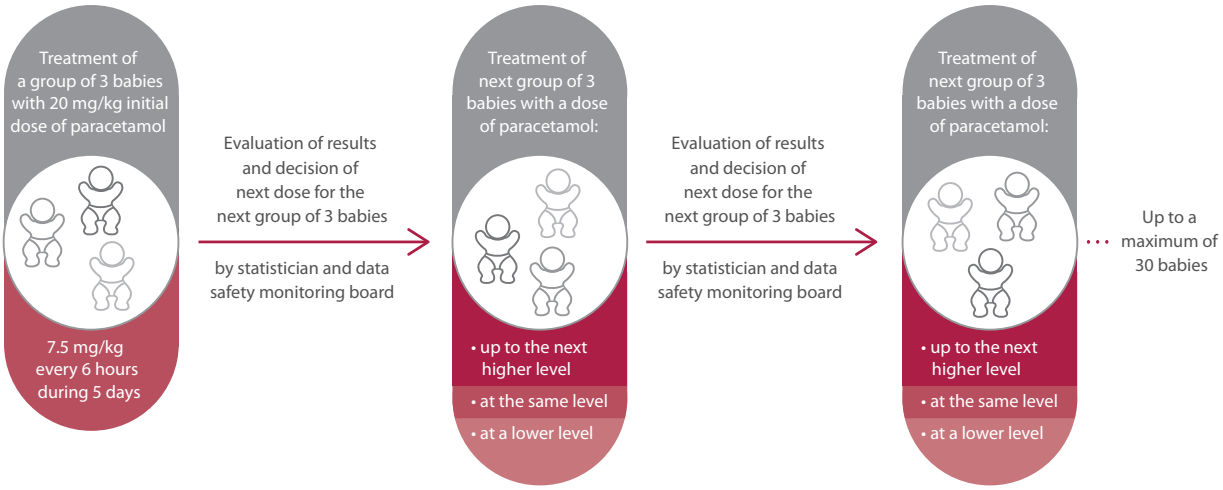
The Ductus Arteriosus is present in all babies before birth and normally closes in the days following birth. However, in about 60% of preterm born babies (born before the completion of 37 weeks of pregnancy), this blood vessel remains open. This is most often the case in the more premature ones. If this 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

The aim of Phase II of this study is to find the minimum dose of paracetamol that closes the ductus arteriosus before or at day 7 after birth in preterm infants born at a gestational age of 23 to 26 weeks. Phase II of this study will be conducted in 10 centres of 4 European countries. A total of 30 preterm babies will be included over a period of 6 months. The entire TREOCAPA trial (Phase II and III) will last 38 months in total.

STUDY PROCEDURE



Study enrolment and the first administration of paracetamol must be given intravenously within the first 12 hours after birth. During the first 5 days of life, further intravenous infusions (placing fluids into the bloodstream through a vein) will follow at 6-hourly intervals for 15 minutes each (total of 20 doses). For the safety of your baby, after the 1st and 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, your baby will be closely monitored during the TREOCAPA trial: the blood pressure of your baby will be measured at 30, 60, 90 and 120 minutes after each infusion, and an ultrasound of the heart is done every day. Blood samples will be taken after dose 1, 10 and 20 to analyse paracetamol concentration in the blood. On the 3rd, 5th and on the 7th day of life and what would have been week 36 of pregnancy (postmenstrual age) or at discharge, medical data will be collected.

POTENTIAL RISKS & BENEFITS

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. Several blood samples will be taken from your child throughout the study. Blood collection is always associated with a very low risk. A slight pain may occur at the site of puncture or a bruise may develop, which will disappear after a few days. In very rare cases, a blood clot (thrombosis) may form, there might be localized inflammation or infection at the site of puncture. In extremely rare cases, damage to blood vessels or nerves may occur.

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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