

# Treatment of Patent Ductus Arteriosus with Paracetamol

ACTRN12613000289718

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Status	RECRUITING
Phase	Phase 3
Sponsor	Sapienza University of Rome
Enrollment	90 participants

## Plain Language Summary

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In premature babies, a blood vessel near the heart called the ductus arteriosus — which is supposed to close naturally after birth — sometimes stays open. This is called patent ductus arteriosus (PDA), and it can cause serious breathing and organ problems. The standard drugs used to close it (NSAIDs like ibuprofen) can cause harmful side effects in premature newborns. This trial is testing whether paracetamol (acetaminophen), a much gentler pain-reliever, can safely close the ductus as an alternative.

You may be eligible if:

- Your baby was born before 32 weeks of pregnancy and weighs less than 1,500 grams
- Ultrasound confirms the ductus arteriosus is still open and causing problems
- Standard NSAID treatments (ibuprofen or indomethacin) have failed or cannot be used

You may NOT be eligible if:

- Your baby has liver disease
- Your baby has haemolytic anaemia
- There is a family history of G6PD deficiency

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

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### Inclusion (1)

- Neonates with gestational age < 32 weeks and birth weight < 1500 g and with echocardiographic evidence of patent ductus arteriosus and contraindication to or failure of conventional medical therapy with COX inhibitors (ibuprofen or indomethacin) consecutively observed in Neonatal Intensive Care Unit are eligible for the trial. In all infants, color-doppler ultrasound will be performed at 24-48 hrs after birth to evaluate patency of ductus arteriosus and shunting. Eligibility of a neonate is defined by the presence at color-doppler ultrasound of at least one of the following criteria: 1. transductal diameter  $\geq$  1.5 mm, 2. reverse diastolic flow or absent diastolic flow in the descending aorta or in the superior mesenteric artery, anterior or middle cerebral arteries or renal artery, 3. unrestrictive pulsatile transductal flow (DA V max < 2 m/s), 4. left-atrium-to-aortic-root ratio  $\geq$  1.5. Contraindications to NSAIDs therapy are: reduced urine output (< 1 ml/kg/h) during the preceding 8 hours or other signs of renal failure, liver failure, intraventricular hemorrhage, a platelet count < 60,000/mm<sup>3</sup>, hyperbilirubinemia (defined as total bilirubin > 15 mg/dl), gastrointestinal bleeding and signs of feeding intolerance. Failure of NSAIDs treatment is defined by the presence of a patent ductus at the end of a single course of treatment with ibuprofen (loading dose at 10 mg/kg, followed by 5 mg/kg at 24 and 48 hours) or indomethacin (three doses at 0,2 mg/kg every 12 hours).

### Exclusion (1)

- Liver disease, hemolytic anemia, family history of G6PD deficiency

## Locations (1 total)

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Italy

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12613000289718>

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