Paracetamol and Patent Ductus Arteriosus closure: Pharmacokinetic-Pharmacodynamic study

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Status	RECRUITING
Sponsor	Monash Health
Enrollment	50 participants

Plain Language Summary

In premature babies, especially those born before 28 weeks, a small blood vessel called the ductus arteriosus — which is supposed to close naturally after birth — often remains open (patent). This open vessel, known as a patent ductus arteriosus (PDA), can put extra strain on the heart and lungs. Paracetamol (acetaminophen) is used to help close this vessel, but it doesn't work in about a third of cases. One reason might be that the dose currently used is not high enough for some babies. This study aims to measure paracetamol levels in premature babies' blood over time to understand how the drug moves through tiny bodies and find the concentration needed to successfully close the PDA.

By building a detailed pharmacokinetic-pharmacodynamic model, researchers hope to be able to tailor doses in the future for better outcomes. Babies already receiving paracetamol as part of their standard care will have small additional blood samples collected.

Your baby may be eligible if they were born before 28 weeks of pregnancy and have been found on an echocardiogram (heart ultrasound) to have a haemodynamically significant PDA. Babies without a significant PDA are not eligible.

Key Eligibility Criteria

Inclusion (2)

- Preterm neonate (<28 weeks GA) with haemodynamically significant PDA (hsPDA) determined by echocardiography.
- An echocardiography will be performed using Vivid E95 equipment (GE Vingmed Ultrasound, Horten, Norway). A PDA scoring schema will be calculated using the parameters: PDA size and velocity, PDA:left pulmonary artery ratio, diastolic flow in main and left pulmonary artery, left atria:aortic (LA:Ao) ratio and left ventricular:aortic ratio. Each parameter scores a maximum 3 points, the maximum score being 21

Exclusion (1)

- Preterm neonates (<28wks) without haemodynamically significant PDA

Locations (1 total)

Monash Children's Hospital - Clayton, VIC, Australia