Airway pressure measurements in newborns on non-invasive respiratory support: a feasibility study (AIRPREMO 2 Study)

ACTRN12624001314516

Status	RECRUITING
Sponsor	The Royal Women's Hospital Melbourne
Enrollment	50 participants

Plain Language Summary

Premature babies often need help breathing, and two common forms of support are CPAP (continuous positive airway pressure) and high-flow nasal cannula (HFNC). These treatments work by providing gentle pressure to keep the tiny airways open. However, some of that pressure is lost through leaks at the nose and mouth, so it is difficult to know exactly how much pressure actually reaches the baby's airway. Measuring this 'pharyngeal pressure' more directly could help doctors fine-tune treatment.

This feasibility study is testing a modified feeding tube that has been adapted to also measure airway pressure in the throat, alongside a new pressure monitoring device. Babies who already need a feeding tube as part of their care can have this modified tube used instead, with pressure measured over several days. The study will check that the device is safe and works as intended.

Your baby may be eligible if they are admitted to the Royal Women's Hospital Neonatal Intensive Care Unit, weigh at least 1 kilogram, are receiving CPAP or high-flow support, and already need a feeding tube as part of their medical care. Babies with structural abnormalities of the nose or throat are not eligible.

Key Eligibility Criteria

Inclusion (1)

- Babies with a current weight of 1 kg or more treated at the Royal Women's Hospital Neonatal Intensive Care Unit receiving non-invasive respiratory support (CPAP or HF), requiring an orogastric or nasogastric feeding tube (for enteral feeding, gastric decompression and/or medication administration) and considered clinically appropriate for study enrolment as per the assessment of the treating neonatal consultant. Note: There will be a lead-in phase of the study, with the first 5 participants recruited weighing 1.5kg or more.

Exclusion (3)

- Weight less than 1 kg.
- Concurrent study that prohibits participation.
- Anatomical anomaly of the nose, mouth, palate, neck, nasal or pharyngeal airway.

Locations (1 total)

The Royal Women's Hospital - Parkville, VIC, Australia