In extremely preterm infants less than 28 weeks gestation who are receiving invasive mechanical ventilation, does extubation to a higher level of continuous positive airway pressure compared to standard practice prevent deterioration and return to mechanical ventilation.

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Status	RECRUITING
Sponsor	Anna M Kidman
Enrollment	200 participants

Plain Language Summary

Very premature babies — those born before 28 weeks of pregnancy — often need mechanical ventilation (a breathing machine) in the days after birth because their lungs are not yet mature enough to breathe independently. When doctors feel a baby is ready, they remove the breathing tube — a process called extubation — and switch the baby to a gentler form of breathing support called nasal CPAP, which delivers a constant gentle pressure to keep tiny airways open. However, many babies need to be re-intubated because they cannot manage on their own, which is stressful and carries risks.

This study tests whether using a higher CPAP pressure (10 cm of water pressure) when babies are first taken off the ventilator reduces the chances of them needing to go back on it, compared to the standard pressure (around 6-8 cm). Two hundred extremely preterm babies will be randomly assigned to one of the two pressure levels immediately after their first extubation.

To be eligible the baby must have been born before 28 weeks gestation, be receiving mechanical ventilation, and be ready for their first extubation attempt. Babies with major congenital abnormalities affecting breathing, or those receiving palliative rather than intensive care, are not eligible. This study is conducted in neonatal intensive care units across multiple hospitals.

Key Eligibility Criteria

Inclusion (4)

- are born less than 28 weeks' gestation
- are being extubated for the first time from mechanical ventilation to nasal CPAP
- have received enteral or intravenous caffeine within 24 hours prior to the planned extubation
- have received surfactant

Exclusion (4)

- Are being extubated to any other mode of non-invasive respiratory support other than CPAP, or to no respiratory support
- Have a major congenital anomaly or condition that might have an adverse effect on breathing or ventilation: known upper airway obstruction or major airway abnormality, or major congenital heart disease
- Are 36 weeks or greater corrected age at time of extubation
- Are not receiving full intensive care after extubation

Locations (3 total)

The Royal Women's Hospital - Parkville, VIC, Australia
Monash Children's Hospital - Clayton, VIC, Australia
Mater Mother's Hospital - South Brisbane, VIC, Australia

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618001638224