

A first in human study for a new resuscitation monitor for newborn babies requiring resuscitation at birth

ACTRN12622000250730

Status	RECRUITING
Sponsor	ResusRight Pty Ltd
Enrollment	30 participants

Plain Language Summary

When newborn babies do not breathe well after birth, doctors and midwives need to help them breathe using a face mask — a process called positive pressure ventilation (PPV). Doing this effectively depends on getting a good seal between the mask and the baby's face, which can be difficult. The NEMO monitor is a new device designed to give real-time feedback to the clinician about how well the mask is sealing, potentially improving how effectively the baby is being helped to breathe.

This first-in-human study will test whether the NEMO monitor is safe to use during actual baby resuscitations, having previously only been tested on training mannequins. Babies who need PPV at birth, and babies in the neonatal intensive care unit who need mask-assisted breathing before a breathing tube is placed, will be enrolled.

Eligibility is for newborn babies born from 30 weeks gestation who need breathing support at birth, or babies from 26 weeks gestation in the NICU needing mask ventilation. Babies with serious birth abnormalities or where a senior resuscitator is unavailable are excluded. Clinician participants must be experienced neonatal medical officers who have completed specific NEMO training.

Key Eligibility Criteria

Inclusion (11)

- Neonatal participants: There are two groups of neonatal participants for this study.
- Neonatal Group 1 - Resuscitation at birth
- Neonates born from 30 weeks gestation that require manual positive pressure ventilation during resuscitation following birth will be recruited to the study.
- Neonatal Group 2 - Neonatal Intensive Care Neonates
- Neonates from 26 weeks gestation that are admitted to the NICU that require manual
- ... and 6 more (see full listing online)

Exclusion (4)

- i. Born with a potentially lethal congenital abnormality.
- ii. Acute, severe, fetal compromise indicating intrapartum still birth (e.g., cessation of fetal heart rate).
- iii. Unavailability of independent senior resuscitator.
- iv. Unavailability of research team.

Locations (2 total)

Westmead Hospital - Westmead, NSW, Australia
Royal Hospital for Women - Randwick, NSW, Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12622000250730>

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