

# Controlled oxygen administration in term newborns and young infants requiring mechanical respiratory support and oxygen therapy

ACTRN12619000742178

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Status	RECRUITING
Sponsor	Murdoch Childrens Research Institute
Enrollment	70 participants

## Plain Language Summary

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Managing oxygen levels in sick newborns and young infants is one of the most delicate aspects of neonatal care. Too little oxygen (hypoxia) can damage organs, but too much (hyperoxia) can harm the eyes and lungs. Nurses and doctors currently adjust oxygen levels manually by reading monitors and tweaking a dial — but this is difficult to get right consistently, especially over many hours.

The COATI study tests whether a computer algorithm called OxyGenie — built into the SLE6000 ventilator — can manage oxygen levels more accurately than manual adjustments. Two groups of babies are included: term newborns with breathing problems from conditions like respiratory distress syndrome or pulmonary hypertension, and younger infants with breathing difficulties caused by respiratory infections. Each baby will receive both manual and automated oxygen control for 12-hour periods (in random order), and the researchers will measure how much time is spent within the target oxygen range.

Eligibility is open to newborns and young infants requiring breathing support and supplemental oxygen in a neonatal or paediatric intensive care unit. Babies with life-threatening instability or those expected to need a change in breathing support soon are excluded. If automated oxygen control proves superior, it could become standard practice in neonatal units around Australia.

## Key Eligibility Criteria

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### Inclusion (16)

- Term newborns with hypoxic respiratory failure, and young infants with respiratory insufficiency related to respiratory tract infection, fulfilling the eligibility criteria outlined below.
- Each participant must meet all of the following criteria in either study population ('Study group A' or Study group B') to be enrolled in the study.
- Study group A: Term and near-term infants requiring mechanical respiratory support and oxygen therapy of any duration due to hypoxic respiratory failure (HRF).
- Gestation at birth greater than or equal to 35 completed weeks.
- Chronological age less than or equal to 2 months.

... and 11 more (see full listing online)

### Exclusion (2)

- Cardiorespiratory instability that precludes entry into a study.
- Change in mode of respiratory support anticipated in next 24 hours.

## Locations (1 total)

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The Royal Childrens Hospital - Parkville, VIC, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12619000742178>

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