

# Human Amnion Epithelial Cells for Prevention of Bronchopulmonary Dysplasia in Preterm Infants: A Safety Study

ACTRN12618000920291

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Status	RECRUITING
Phase	Phase 1
Sponsor	Monash Health
Enrollment	24 participants

## Plain Language Summary

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Thanks to advances in neonatal care, more babies born very prematurely — especially before 29 weeks — are surviving than ever before. However, many of these tiny babies develop a serious lung condition called bronchopulmonary dysplasia (BPD), where the lungs are damaged by the intensive care interventions needed to keep them alive. BPD can affect breathing and brain development long into childhood, and despite decades of research, rates have not improved.

This trial is testing a promising new therapy: human amnion epithelial cells (hAECs), which are cells derived from the inner lining of the placenta. In animal studies, these cells have shown a remarkable ability to calm lung inflammation and help damaged lungs heal. A small earlier study showed the cells appeared safe in babies with established BPD. This new study is testing higher doses given earlier — before BPD is fully established — to see if they can prevent it.

This study is for extremely premature babies (born before 29 weeks) who are still needing significant breathing support by day 14 of life. The treatment is given intravenously in the third and fourth week. As this is a safety study for a new therapy, eligibility is assessed by the clinical team on a case-by-case basis.

## Key Eligibility Criteria

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### Inclusion (2)

- Born <29 weeks gestation
- Ventilated via an endotracheal tube requiring greater than or equal to 25% oxygen or receiving non-invasive respiratory support requiring greater than or equal to 35% oxygen on day 14 of life to maintain oxygen saturations in range 90-94%.

### Exclusion (6)

- clinical team consider death imminent or full intensive care is not being offered
- significant congenital abnormality, including but not limited to
  - o severe congenital heart disease
  - o congenital airway malformation
  - o severe neurological abnormality
- ... and 1 more (see full listing online)

## Locations (2 total)

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Monash Children's Hospital - Clayton, VIC, Australia  
The Royal Women's Hospital - Parkville, VIC, Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12618000920291>

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