

# Intravenous pentoxifylline as adjunct therapy to improve long-term disability in preterm infants

ACTRN12616000405415

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 3
<b>Sponsor</b>	University of Sydney
<b>Enrollment</b>	1,800 participants

## Plain Language Summary

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This trial is testing whether a medication called pentoxifylline can help very premature babies — those born before 29 weeks — survive without disability. When premature babies get a serious infection (called late-onset sepsis) or a bowel condition (called necrotising enterocolitis), their whole body can become dangerously inflamed. Pentoxifylline is a safe, inexpensive drug that may help calm this inflammation and reduce the risk of brain injury. This is a large international trial enrolling about 1,800 premature infants.

You may be eligible if:

- Your baby was born before 29 weeks of pregnancy
- Your baby is being treated for suspected late-onset sepsis or necrotising enterocolitis
- Enrolment happens within 6 hours of the blood culture being taken (and no later than 12 hours)
- You as the parent are willing and able to provide informed consent

You may NOT be eligible if:

- Your baby has a congenital malformation, chromosomal abnormality, or another condition considered incompatible with surviving to 24 months without disability

Talk to your doctor about whether this trial might be right for you.

## Key Eligibility Criteria

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### Inclusion (3)

- Gestation <29 weeks at birth.
- < 6 hours (no later than 12 hours) from blood culture taken for suspected late-onset sepsis or NEC.
- Informed parental consent.

### Exclusion (1)

- Congenital malformations, chromosomal abnormalities or any other condition considered incompatible with disability-free survival at 24 months of age.

## Locations (25 total)

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King Edward Memorial Hospital - Subiaco, ACT,NSW,QLD,SA,TAS,WA,VIC, Australia  
Royal Prince Alfred Hospital - Camperdown, ACT,NSW,QLD,SA,TAS,WA,VIC, Australia  
Nepean Hospital - Kingswood, ACT,NSW,QLD,SA,TAS,WA,VIC, Australia  
... and 22 more locations

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12616000405415>

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