

# Melatonin to prevent brain injury in unborn growth restricted babies

ACTRN12612000858897

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Status	RECRUITING
Phase	Phase 4
Sponsor	Monash University
Enrollment	12 participants

## Plain Language Summary

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This study tests whether melatonin taken twice daily during pregnancy can protect the brain of an unborn baby that is not growing properly (called intrauterine growth restriction, or IUGR). When a baby does not get enough oxygen in the womb, it can cause oxidative stress that damages developing organs. Melatonin is a naturally occurring hormone that has been shown in animal studies to reduce this damage.

You may be eligible if:

- You are pregnant and aged 18 to 45
- Your baby is measuring below the 10th percentile for size with abnormal blood flow on ultrasound
- You are carrying a single baby
- You are between 23 and 34 weeks pregnant
- Your baby has a normal anatomy scan and there is no immediate need to deliver
- You have a basic understanding of English

You may NOT be eligible if:

- You are carrying twins or more
- Your baby has a known chromosome abnormality or birth defect
- The cause of your baby's small size is not related to the placenta
- The length of your pregnancy is not confirmed

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

## Key Eligibility Criteria

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### Inclusion (10)

- Estimated fetal weight <10th percentile in combination with abnormal fetoplacental Doppler studies.
  - Singleton pregnancy
  - Live fetus
  - Gestational age: from 23+0 weeks until 34+0 weeks
  - Normal fetal anatomy on ultrasound
- ... and 5 more (see full listing online)

### Exclusion (6)

- Fetal demise
- Multiple pregnancy
- Known abnormal karyotype
- Presence of any congenital abnormality
- Unknown duration of pregnancy

... and 1 more (see full listing online)

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12612000858897>

### Locations (1 total)

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