

# Exogenous Melatonin to Improve Sleep in Critically Ill Patients

ACTRN1261000008022

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Status	RECRUITING
Phase	Phase 3, Phase 4
Sponsor	The Alfred
Enrollment	60 participants

## Plain Language Summary

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This study is looking at whether giving melatonin — a natural sleep hormone — at night can help critically ill patients in the intensive care unit (ICU) sleep better. Patients in the ICU often have disrupted sleep, which can slow recovery. This trial will give patients who have a tracheostomy (breathing tube in the throat) either melatonin or a placebo (dummy pill) along with their usual sleep medication for one week.

You may be eligible if:

- You are 18 years of age or older
- You are admitted to the ICU
- You have a tracheostomy to help wean you off a ventilator (breathing machine)
- Your Glasgow Coma Scale score is 12 or higher (meaning you are alert enough to communicate)
- You are having trouble sleeping (fewer than 4 hours of night-time sleep or 4 or more wake-ups per night)

You may NOT be eligible if:

- You are on a continuous sedative drip
- You have a reason you cannot take medicines by mouth or feeding tube
- You are pregnant or breastfeeding

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

## Key Eligibility Criteria

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### Inclusion (4)

- Patients 18 years and older admitted to the ICU
- Tracheostomy for weaning of ventilation
- Glasgow Coma Scale (GCS) equal to or greater than 12
- Difficulty sleeping as reported by patient or medical staff - 4 or less hours of nocturnal sleep and/or 4 or more awakenings overnight

### Exclusion (3)

- Patients on sedative infusions
- Contraindications to enteral feeding and/or administration of medications
- Pregnant or breast-feeding

## Locations (1 total)

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Australia

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<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN1261000008022>

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