The SuDDICU Study of Antibiotic Prophylaxis in Critical Illness

ACTRN12615000411549

Status	RECRUITING
Phase	Phase 3
Sponsor	The George Institute for Global Health
Enrollment	15,000 participants

Plain Language Summary

This study is testing a treatment called Selective Decontamination of the Digestive Tract (SDD) for patients who are seriously ill in the intensive care unit (ICU) and on a breathing machine. SDD uses antibiotics and antifungal medicine applied to the throat and stomach, along with a short course of IV antibiotics, to reduce the risk of dangerous infections.

You may be eligible if:
- You are 16 years of age or older
- You are on a mechanical ventilator (breathing machine) through a tube in your throat
- You are expected to remain on the ventilator for more than one day
- You are a patient in a general ICU participating in the study

You may NOT be eligible if:
- You are enrolled in another trial that would interfere with this treatment
- You have a known allergy to the antibiotic or antifungal medicines used
- You are known or suspected to be pregnant
- You are not expected to survive the next 12 hours
- You are under 16 years of age (in the UK)

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

Key Eligibility Criteria

Inclusion (5)

- Site inclusion for cluster study:
- A general ICU or complex of ICUs (medical, surgical, mixed) capable of treating mechanically ventilated critically ill patients.
- All patients who are mechanically ventilated via an endotracheal tube on admission to ICU and who are predicted to remain ventilated beyond the end of the calendar day after the day of ICU admission, or
- All patients who become mechanically ventilated via an endotracheal tube during their ICU stay and who are predicted to remain ventilated beyond the end of the calendar day after the day they are first ventilated, or
- All patients not already recruited who are receiving mechanical ventilation via an endotracheal tube and are expected to receive ongoing ventilation for a further 48 hours or more despite an earlier prediction that ventilation would be discontinued earlier.

Exclusion (9)

- Unwilling or unable to follow trial protocols.
- Unable to capture the minimum data set required for the study.
- Isolated specialty ICUs (non co-located with a general ICU) such as solely cardiac, neurological/neurosurgical and burns ICUs (but such specialty patients cared for in general ICUs will be included).
- Specialty paediatric ICUs
- Patients enrolled in a trial that would interact with the intervention

... and 4 more (see full listing online)

https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12615000411549

Locations (18 total)

Royal North Shore Hospital - St Leonards, NSW,QLD,SA,VIC, Australia
Nepean Hospital - Kingswood, NSW,QLD,SA,VIC, Australia
Gosford Hospital - Gosford, NSW,QLD,SA,VIC, Australia
... and 15 more locations