

A double blind randomised placebo-controlled intervention trial to determine the efficacy of the probiotic VSL #3 in reducing the incidence and or frequency of diarrhoea in enterally-fed critically ill patients.

ACTRN12605000167662

Status	RECRUITING
Phase	Phase 1
Sponsor	Department of Health and Human Services (Tasmanian Government)
Enrollment	100 participants

Plain Language Summary

This study looks at whether a probiotic supplement (containing beneficial bacteria, similar to what is found in yoghurt) can reduce diarrhoea in critically ill adults who are receiving nutrition through a feeding tube in an intensive care unit (ICU). Probiotics are thought to help restore healthy gut bacteria and may also lower the risk of infections.

You may be eligible if:

- You are 18 years of age or older
- You are a patient admitted to the ICU and are expected to need tube feeding for at least 48 hours

You may NOT be eligible if:

- You are under 18 years old
- You are expected to only need tube feeding for less than 48 hours
- You have a known allergy to dairy/milk preparations
- You have special dietary requirements that require intravenous nutrition (TPN) instead of tube feeding
- You have a blockage or condition preventing tube feeding

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

Key Eligibility Criteria

Inclusion (1)

- All prospective adult participants that may require tube feeding as part of their routine management of their illness while a patient admitted to the ICU will be screened preoperatively in the pre-admission clinic or on admission to the ICU.

Exclusion (1)

- Patients with the following characteristics would be excluded from the study; < 18 years Likely to be tube fed < 48 hours Allergy to milk preparations Present with special dietary requirements (other than diabetic or renal considerations) requiring Total Parenteral Nutrition (TPN) Present with any condition that might interfere with the delivery of enteral feeds such as obstruction of the gastrointestinal tract.

Locations (1 total)

Australia

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12605000167662>

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