

Gut Bugs for C. Difficile Infection

ACTRN12624000133538

Status	RECRUITING
Phase	Phase 3
Sponsor	University of Auckland
Enrollment	84 participants

Plain Language Summary

Clostridioides difficile (C. diff) is a stubborn gut infection that causes severe diarrhoea and keeps coming back in many people, often after antibiotic treatment. Standard antibiotic treatment only leads to long-term cure in about 30-35% of recurrent cases, which is why researchers are investigating faecal microbiota transplantation (FMT) — a treatment where stool from a healthy donor is transplanted into the patient's gut to restore a healthy bacterial balance.

This randomised controlled trial compares three treatment approaches: FMT capsules alone, the antibiotic vancomycin alone, or vancomycin followed by FMT. Participants are randomly assigned to one of these groups and followed for 12 weeks, with assessments of gut symptoms, wellbeing, and quality of life.

You may be eligible if you are aged 16 to 90, can swallow capsules, and have had a first episode, first recurrence, or refractory (treatment-resistant) C. difficile infection. People currently on antibiotics for other reasons or with severe active C. diff infection may not be eligible. This trial could help establish FMT as a first-line treatment for recurrent C. diff.

Key Eligibility Criteria

Inclusion (6)

- Aged 16 to 90 years; AND
 - Ability to swallow all treatment capsules; AND
 - Having:
 - a. First episode *Clostridioides difficile* infection; OR
 - b. First Recurrent *Clostridioides difficile* infection; OR
- ... and 1 more (see full listing online)

Exclusion (6)

- Current systemic antibiotic treatment except if prescribed for *Clostridioides difficile* infection
 - Severe allergy to foods and/or common medications
 - Current hospitalisation because of severe *Clostridioides difficile* infection, defined as having at least one of the following that is not directly attributable to a non-*Clostridioides difficile* infection illness (e.g., infection):
 - a. Fever (core body temperature of greater than 38.5°C);
 - b. Marked leukocytosis (leucocyte count greater than 15 x10⁹/L);
- ... and 1 more (see full listing online)

Locations (1 total)

New Zealand

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000133538>

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