A Novel Device for Refeeding output in Stoma and Fistula Patients

ACTRN12618001095257

Status	RECRUITING
Sponsor	Asscociate Professor Gregory O' Grady
Enrollment	15 participants

Plain Language Summary

Patients who have had bowel surgery and end up with a loop ileostomy (a stoma where bowel contents exit through the abdomen) or an enterocutaneous fistula (an abnormal opening between the bowel and skin) can lose large amounts of fluid and important minerals through their stoma output. This can cause serious electrolyte imbalances and slow recovery. One way to address this is to collect the stoma output and pump it back further down the bowel — a process called refeeding.

This feasibility study is testing a new device designed to make this refeeding process practical and manageable for patients. The study will assess how well the device works, how easy it is to use, and how patients feel about using it. Participants will keep a daily diary about the device and be interviewed about their experience.

You may be eligible if you are an adult (18 or older) with a defunctioning loop ileostomy or an enterocutaneous fistula, and have had tests to confirm there is no blockage or leakage in the bowel that would make the procedure unsafe. Immunocompromised patients, pregnant women, and those with Clostridium difficile infection would not be eligible.

Key Eligibility Criteria

Inclusion (4)

- Adults (>18 years of age).
- Have a defunctioning loop ileostomy or enterocutaneous fistula
- Able to understand risks and benefits of participating in the study.
- Anastomotic leak and distal obstruction excluded on gastrograffin study or CT with contrast.

Exclusion (8)

- Immunocompromise
- Pregnancy
- Previous or current Clostridium difficile colitis
- Distal obstruction
- Anastomotic leak or perforation

... and 3 more (see full listing online)

Locations (1 total)

North Island, New Zealand

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at anzctr.org.au. Generated by ClinicalTrialsFinder.org.