

Enhancing automated chyme reinfusion therapy with The Insides System

ACTRN12624000427572

Status	RECRUITING
Sponsor	The Insides Company
Enrollment	50 participants

Plain Language Summary

This feasibility study by The Insides Company is testing an updated version of their automated chyme reinfusion therapy system. 'Chyme reinfusion' is a medical technique used for people with a loop or double-barrel stoma (an opening in the abdomen where the bowel has been brought to the surface after surgery). Rather than losing digestive fluid (chyme) through the stoma, the device recycles it back into the lower part of the bowel — helping nutrition and gut healing.

The updated version of The Insides System incorporates improvements based on feedback from patients and clinicians internationally. This study aims to confirm that the updated device is safe, effective, and acceptable to use.

You may be eligible if you are 18 or older, have a loop, double-barrel, or similar small bowel stoma (or an enterocutaneous fistula), can manage your stoma independently, and are able to give informed consent. Patients with an anastomotic leak, obstruction in the lower bowel, current pregnancy, or a history of *C. difficile* colitis would not be eligible.

Key Eligibility Criteria

Inclusion (8)

- Adults ≥ 18 years of age, with defunctioning loop/double barrel/abcarian small bowel stoma or enterocutaneous fistula
- If colonic anastomosis present, anastomotic leak and distal obstruction will be excluded e.g. via gastrografen enema or CT scan with rectal contrast or clinical evaluation such as endoscopy
- If ECF patient, gastrografen enema or CT scan with rectal contrast or clinical evaluation such as endoscopy to ensure patent distal intestine
- Distal limb of stoma can be intubated with a minimum of 22 Fr feeding tube (dilatation of stoma orifice strictures is allowable)
- Able to independently manage their stoma

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

Exclusion (9)

- < 18 years of age
- Anastomotic leak or perforation
- Insufficient distal access or distal obstruction
- Current pregnancy
- Separated proximal and distal stomas that are pouched with separate ostomy appliances

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

Locations (1 total)

New Zealand

<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12624000427572>

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