Efficacy and Safety of Multiple Faecal Microbiota Transfers in Acute Pouchitis

Published: 28-04-2020
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To study the effectiveness and safety of administration of FMT on acute pouchitis.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON49333

Source
ToetsingOnline

Brief title
FMT-pouchitis

Condition

- Gastrointestinal inflammatory conditions

Synonym
inflammation of the pouch reservoir, Pouchitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: MLDS

Intervention

Keyword: Fecal microbiota transfer, FMT, Pouchitis, Ulcerative colitis

Outcome measures

Primary outcome

The primary endpoint is the proportion of patients in clinical and endoscopic remission at week 8.

Secondary outcome

The main secondary endpoints are antibiotic-free clinical and endoscopic remission at week 52, and changes in microbiota signature, functional profiling as well as metabolic output from baseline to week 8 and week 52.

To study the speed of clinical remission induction of pouchitis after FMT.

Study description

Background summary

Pouchitis is defined as inflammation of the ileal pouch reservoir and is the most frequent complication in patients with an ileal pouch anal anastomosis (IPAA) after rectoproctocolectomy (RPC) for ulcerative colitis (UC). The cumulative incidence of pouchitis has been reported to be as high as 59% in UC patients(1, 2). However, the pathophysiology of pouchitis is not completely understood. Increasing evidence suggests the microbiome plays a key role in the pathogenesis of pouchitis. Clinical effectiveness of broad-spectrum antibiotics such as metronidazole and ciprofloxacin implies bacteria play an important role in the development of pouchitis(3, 4). To support this dysbiosis hypothesis, pouchitis usually only occurs after ileostomy closure, suggesting exposure to the faecal stream, and subsequently the microbiome, plays a key role in the pathogenesis of pouchitis.
Taking this information into account, treating pouchitis by modulating the microbiome might be an attractive solution in pouch patients. A potential approach to accomplish this is by faecal microbiota transfer (FMT). FMT has proved to be successful in treating Clostridium difficile infections and is gaining popularity in inflammatory bowel diseases (IBD) as well.

Study objective

To study the effectiveness and safety of administration of FMT on acute

pouchitis.

Study design

Single arm, proof of concept clinical trial in which 20 patients will be included.

Intervention

Patients will receive a multiple faecal microbiota transfers from healthy, carefully selected donors.

Study burden and risks

Total follow-up time will be 52 weeks, during which 7 study visits are planned. FMT will be administered by nasojejunal tube at week 0 and week 3 as well as by retention enema at week 0, 1, 2, and 3. Nasojejunal tube placement will be performed by a Cortrak pro-cedure. This is a routine procedure in our centres and is associated with a very small risk of complications. The same applies to pouchoscopies, which patients will have to undergo three times with biopsies. From our earlier trials we know that nasojejunal FMT administration is well tolerated. In the TURN trial conducted previously in the Amsterdam UMC, one in 100 administrations resulted in vomiting, which amounts to a total of two occurrences. Most patients complained of transient borborygmi and in two patients transient fever was seen. No serious adverse events attributable to FMT have been encountered with nasojejunal FMT administration in over 500 study subjects in the Amsterdam UMC.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• IPAA for ulcerative colitis
• Episode of acute pouchitis, defined as a PDAI >= 7, and endoscopic subscore of > 2
• History of at least one episode of pouchitis, which necessitated antibiotic treatment.

Exclusion criteria

- Pouchitis due to surgery related conditions (i.e. abscess, fistula. sinus of the pouch), identified by endoscopic assessment of the pouch
- Crohn's Disease
- Patients with signs of severe systemic inflammation (at least two of the following symptoms: temperature > 38.5 *C, tachycardia > 100 bpm (after rehydration), systolic blood pressure < 100 mmHg).
- Patients with severe pouchitis on endoscopy who require immediate intervention, based on the discretion of the endoscopist.
- Mechanical complications of the pouch (i.e. pouch stricture, pouch fistula)
- Diverting ileostomy
- Use of systemic antibiotic or probiotic therapy in the preceding 4 weeks.
- Use of concurrent anti-inflammatory drugs (i.e. thiopurines, anti-TNF, corticosteroids, etc.)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-04-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL71381.018.20

Register	ID
Other	NL7770