Transplantation of Feces in Acute Pouchitis

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23583

Source
NTR

Brief title
FMT-Pouchitis

Health condition

Acute pouchitis

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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. In this study, patients who present with an episode of acute pouchitis will be treated with FMT for four consecutive weeks (by enema and nasojejunal tube administration).

Study objective

We hypothesize that FMT from a healthy donor will modulate the microbiome of the pouch of patients with ulcerative colitis, and will thereby resolve the inflammation of the pouch.

Study design

-1, 0, 1, 2, 3, 4, 8, 26, 52

Intervention

Faecal microbiota transfer (FMT), administered by rectal enema and nasojejunal tube infusion.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥18 and <70.
2. Ability to give informed consent.
3. IPAA for ulcerative colitis completed at least 4 months prior to inclusion in this study.
4. Episode of acute pouchitis, defined as a mPDAI ≥ 5, and endoscopic subscore of ≥ 2.
5. History of at least one earlier episode of pouchitis, which necessitated antibiotic treatment.
6. Women in their reproductive age period are required to use reliable contraception during participation in this study.

Exclusion criteria

1. Pouchitis due to surgery-related conditions (i.e. abscess, fistula, sinus of the pouch), identified by endoscopic assessment of the pouch.
2. Crohn's disease.
3. Patients with signs of severe systemic inflammation (at least two of the following symptoms: temperature > 38.5 ^{0}C, tachycardia > 100 bpm (after rehydration), systolic blood pressure < 100 mmHg).
4. Patients with severe pouchitis on endoscopy who require immediate intervention, based on the discretion of the endoscopist.
5. Mechanical complications of the pouch (e.g. pouch stricture or pouch fistula).
6. Diverting ileostomy.
7. Condition leading to profound immunosuppression;
a. For example: HIV, infectious diseases leading to immunosuppression, bone marrow malignancies,
b. Use of systemic chemotherapy,
c. Child-Pugh B/C liver cirrhosis.
8. Use of systemic antibiotic therapy in the preceding 4 weeks.
9. Use of probiotic treatment in the preceding 4 weeks.

10. Use of concurrent anti-inflammatory drugs, e.g. thiopurines, anti-TNF, Vedolizumab. Ustekinumab, JAK-inhibitors, cyclosporine, methotrexate, prednisolone or topical treat-ment in the preceding 2 months before inclusion.
11. Life expectancy < 12 months.
12. Difficulty with swallowing.
13. Positive stool cultures for common enteric pathogens (Salmonella, Shigella, Yersinia, Campylobacter, enteropathogenic E. coli).
14. Positive C. Difficile stool test
15. Positive dual faeces test for pathogenic parasites e.g. Dientamoeba histolytica, Giar-dia Lamblia, Dientamoeba fragilis, Blastocystis hominis only if microscopically many or very many blastocysts are seen.
16. Pregnancy or women who give breastfeeding.
17. Vasopressive medication, intensive care stay.
18. Signs of ileus, diminished passage.
19. Allergy to macrogol or substituents, e.g. peanuts, shellfish.
20. Subject who has any condition that in the opinion of the investigator, would compro-mise the safety of the subject or the quality of the data and is an unsuitable candidate for the study.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-08-2020
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-08-2020
Application type:	First submission

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
NTR-new	NL8817
Other	METC AMC : METC 2020_039

Study results