Transplantation of Feces in Acute Pouchitis

Gepubliceerd: 06-08-2020 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23583

Bron
Nationaal Trial Register

Verkorte titel
FMT-Pouchitis

Aandoening

Acute pouchitis

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The proportion of patients in clinical and endoscopic remission at week 8

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Amsterdam UMC, location AMC
Djuna de Jong

020-5661260

Wetenschappelijk

Amsterdam UMC, location AMC
Djuna de Jong

020-5661260

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-08-2020
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	06-08-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8817
Ander register	METC AMC : METC 2020_039

Resultaten