Effects of bowel lavage on engraftment in irratble bowel patients treated with fecal microbiota transplantation

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Primary objective: to evaluate if bowel lavage prior to donor fecal infusion leads to better engraftment of the donor microbiotaSecondary objective: to follow structural changes in microbiota profile post-FMTSecondary objective: to assess the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal disorders
Study type	Interventional

Summary

ID

NL-OMON48544

Source
ToetsingOnline

Brief title
ENT-Trial

Condition

- Gastrointestinal disorders

Synonym
IBS, Irritable Bowel Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Vedanta Biosciences

Intervention

Keyword: Engraftment, Fecal Microbiota Transplantation, FMT, IBS

Outcome measures

Primary outcome

Main study endpoint: the level of engraftment of donor microbiota in experimental and control patients. Resemblance between donor and recipient microbiota profile post-FMT will be assessed with IS-PRO technique, this is defined as engraftment.

Secondary outcome

Secondary endpoint: changes in microbiota post-FMT. The will be assessed with the IS-PRO technique.

Secondary endpoint: changes in scores on IBS questionnaire post FMT compared to baseline questionnaire score

Study description

Background summary

There is growing interest in the human gut microbiota and its involvement in several gastro-intestinal (GI) disorders and extra intestinal disorders. IBS is on the most common of these disorders affecting between 10-15% of adults in developed countries. There is growing evidence that gut microbiota is involved in the pathogenesis and or the pathophysiology of IBS.

Fecal microbiota transplantation (FMT) is a safe and efficacious treatment for an altered microbiota. The level of engraftment of donor microbiota to the recipient is probably associated with a better treatment outcome. Patients treated with FMT for recurring Clostridium difficile infections receive a bowel lavage prior to treatment. The rationale behind the bowel lavage is that it washes out the C. difficile spores and leads to better engraftment of donor microbiota, however there is little to no evidence that supports this.

Our hypothesis is that treatment with FMT without bowel lavage leads to a similar level of engraftment compared to patients who receive bowel lavage one day prior to FMT.

Study objective

Primary objective: to evaluate if bowel lavage prior to donor fecal infusion leads to better engraftment of the donor microbiota
Secondary objective: to follow structural changes in microbiota profile post-FMT
Secondary objective: to assess the effects of FMT on IBS symptoms

Study design

Randomized controlled, single center, open label trial

Intervention

IBS patients will be treated with FMT to assess the difference in engraftment in patients pre-treated with bowel lavage (conventional arm) compared to patients not pre-treated with bowel lavage (experimental) .
Bowel lavage will be performed by administration of 1 liter Moviprep ® or 2 liters KleanPrep® the day prior to FMT.

Study burden and risks

Colon lavage and insertion of a duodenal tube could cause inconveniency. A recent meta-analysis showed that FMT can lead to serious adverse events, however a closer look into these cases showed that these events should be attributed to the route of administration and not the FMT itself. Main side effects of donor feces infusion can be diarrhea, cramping, belching, nausea, abdominal pain, and dizziness, which resolve within a few days. Participating patients are asked to collect fecal samples, and fill out a an IBS questionnaire before and after FMT. Patients will have brief scheduled telephone contacts at 1 week, 1 month, 3 months, and 6 months after FMT to discuss recovery and presence of recurrence or adverse events. When the fecal samples from the NDFB are delivered at the VUmc, the samples will be stored at -80°C at the department of Medical Microbiology and Infection Prevention until further handling.

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

In order to be eligible to participate in this study, a subject must meet the following criteria:
1. Post-infectious or post antibiotic use IBS, IBS defined by the ROME IV criteria
2. 18 years or older
3. Provide informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Swallowing disorders,
2. Pregnancy,
3. Antibiotics use during study or shortly prior to start of study
4. Need for chemotherapy
5. ICU-admission
6. IBD / Celiac Disease

7. Severe immunecompromisation

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-04-2019
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	09-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-08-2019
Application type:	Amendment
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	NL62455.029.18