Pilot Study of Faecal Microbiota Transplantation in Multiple Sclerosis, a Phase-1 Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system infections and inflammations
Study type	Interventional

Summary

ID

NL-OMON48243

Source
ToetsingOnline

Brief title
POTENTIAL-Trial

Condition

- Central nervous system infections and inflammations

Synonym
MS, Multiple Sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: MS Clinical Research

Intervention

Keyword: Fecal Microbiota Transplantation, FMT, Microbiota, MS, Multiple Sclerosis

Outcome measures

Primary outcome

Primary Objective: To assess the safety of FMT treatment in MS patients,

measured by number of (serious) adverse events, clinical relapses, disease

progression (EDSS), serum neurofilament levels, and MRI.

Secondary outcome

Secondary Objective(s): Systemic response to FMT measured by immunological

parameters (e.g. lipidomics); microbiota dynamics assessed by faecal sampling.

Study description

Background summary

Recent research has implicated dysbiosis (alteration of function and composition of the microbiota) in the gut microbiota in the pathophysiology of MS. The dysbiosis found in MS patients seems to correlate with the distinct immunological findings associated with MS. Restoring dysbiosis could provide a new therapeutic approach in MS.

Study objective

Overall the safety to perform FMT has to be assessed before potential trial powered for efficacy can be performed. In this study we aim to treat 10 patients with different forms of MS to assess if FMT is safe to perform.

Primary Objective: To assess the safety of FMT treatment in MS patients, measured by number of (serious) adverse events, clinical relapses, disease progression (EDSS), serum neurofilament levels, and MRI.

Secondary Objective(s): Systemic response to FMT measured by immunological parameters (e.g. lipidomics); microbiota dynamics assessed by faecal sampling.

Study design

Mono-centre, open-label, interventional clinical pilot study, conducted in Amsterdam UMC, location VU University Medical Center. Estimated start of study is January 2020. The study is expected to be completed within one year.

Intervention

All patients will be treated twice with FMT, after pre-treatment with oral vancomycin and bowel lavage. A single donor will be used for all participants. Faecal suspension will be provided by de Nederlandse Donor Feces Bank (NDFB)

FMT will be performed via endoscopical placement of a duodenal tube. The first FMT will be preceded by a 4 day course of 250 mg vancomycin QID, and a bowellavage.

Study burden and risks

Participants will undergo FMT twice under mild sedation, with an interval of two weeks. Outpatient clinic visits are scheduled before FMT, and one week, one month and six months after FMT. At each visit samples of blood and faeces are collected, questionnaires are completed and a physical examination is performed. Cerebral MRI-scans are made before treatment and after six months. FMT will lead to moderate discomfort during the procedure. FMT is considered to be safe, provided that adequate screening of donors and faeces is assured, as it is in this study. There is extensive experience with FMT in patients with multiple recurrent Clostridium difficile infection. Although these patients are much more vulnerable than the MS patients that we intend to include in this study, serious side effects are rare. In studies with less stringent safety measures serious side effects have been reported. We do not expect a clear benefit for patients participating in this study

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

Diagnosis of MS, currently not on medication for MS

Exclusion criteria

MS-medication
Need for antibiotics
Swallowing disorders

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-09-2021
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-02-2022
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	NL70458.029.19