The possible influences of the gastrointestinal microbiome on fatigue and the disease course of inflammatory bowel disease: a prospective follow-up study

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To study the influence of longitudinal changes in the intestinal microbiome on fatigue, and disease course of Crohn*s disease patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational invasive

Summary

ID

NL-OMON47957

Source
ToetsingOnline

Brief title
MICROBE

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory bowel disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Crohn's disease, Disease course, Fatigue, Microbiome

Outcome measures

Primary outcome

The main study parameter is the composition of the patients* intestinal microbiome defined by the proportion and diversity of fecal bacteria species and phyla, and its effect on fatigue measured by different questionnaires. This will be measured every three months over the course of two years to account for changes in the composition of the microbiome over time.

Secondary outcome

What is the influence of alterations in the intestinal microbiome composition on the course of disease in patients with Crohn's disease?

Anxiety and depression

Quality of life

Disability

Blood parameters

Study description

Background summary

The composition of the intestinal microbiome is believed to be involved in the pathogenesis of chronic diseases, including inflammatory bowel disease (IBD). IBD patients report high rates of moderate to severe fatigue. Evidence suggests

that the intestinal microbiota act as mediator in the bidirectional communication between nervous system and the gut. However, little is known about the changes in the composition of the intestinal microbiome and their influence on fatigue and the course of disease over time.

Study objective

To study the influence of longitudinal changes in the intestinal microbiome on fatigue, and disease course of Crohn*s disease patients.

Study design

This study consists of a longitudinal prospective non-interventional design where a cohort of IBD patients will be followed for a period of two years and variables will be measured every three months.

Study burden and risks

Patients who agree to participate in the study will come to their habitual check-up at the outpatient clinic of the department of Gastroenterology at Erasmus MC every six months. As additional burden, they will be asked to provide a fecal sample and fill out a series of questionnaires during that visit and again three months later. This pattern will be repeated over a period of two years. In addition, patients with an exacerbation of disease will be asked to provide an extra fecal sample and fill out questionnaires at the time of disease onset. The risks associated with this study are low, as no investigational medicinal product will be used.

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

Aged 18 or older
Confirmed Crohn's disease based on diagnostic criteria using clinical symptoms, endoscopic, biochemical and or histological results

Exclusion criteria

-Use of pre-, pro- and/or antibiotics within 8 weeks prior to start of the study
- Presence of active malignancy or dysplasia
- Pregnant and/or breastfeeding women
- Presence of active rotavirus or clostridium infection at start of study
- Patients with a pouch or stoma

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2019
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

Date:	08-11-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL70469.078.19