The vaginal microbiome of fertile inflammatory bowel disease women, a comparison study

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To study the difference between the vaginal microbiome of fertile women with IBD and healthy controls, as determined by lactobacillus dominance.

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

Summary

ID

NL-OMON49339

Source
ToetsingOnline

Brief title
SWAB study

Condition

- Gastrointestinal inflammatory conditions

Synonym
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: Fecal microbiome, Fertility, Inflammatory Bowel Disease (IBD), Vaginal microbiome

Outcome measures

Primary outcome

The main study parameter is the composition of the patients* vaginal microbiome defined by the proportion and diversity of vaginal bacteria species and phyla looking at Lactobacillus dominance, compared to fertile women without IBD, and its associations with the intestinal microbiome.

Secondary outcome

* Is there a correlation between the vaginal microbiome composition and fecal microbiome composition in IBD patients?

* Is the composition of the vaginal microbiome associated with patient characteristics, e.g. diagnosis, disease activity, and vaginal symptoms?

Study description

Background summary

Inflammatory Bowel Disease (IBD) is an umbrella term for Crohn*s disease (CD) and ulcerative colitis (UC), used to describe a chronic gastrointestinal inflammation. IBD is often characterized by unpredictable flares between periods of remission. Intermittent inflammation of the gastrointestinal tract can cause abdominal pain and cramping, diarrhea, blood in the stool, unintentional weight loss and extreme tiredness. The intestinal microbiome is widely studied in IBD, but less is known about the vaginal microbiome. The vaginal microbiome is a very dynamic ecosystem that consists of diverse microorganisms, the composition of which is subject to change because of sexual activity, menstruation and diseases like bacterial vaginosis. In healthy reproductive-aged woman, the vaginal mucosa is predominantly populated by Lactobaccilus spp which produce lactic acid. As a result, the low pH in the vaginal mucosa forms a barrier for pathogenic agents from the outside world.

Recently, several studies have indicated the effect of vaginal microbiome on the fertility and pregnancy outcomes of women in the reproductive phase. At this moment, very little is known about the make-up of the vaginal microbiome in IBD patients, highlighting the need for more research on this particular topic. Therefore, our main goal is to investigate the difference in the composition of vaginal microbiota between reproductive-aged woman with IBD and healthy controls.

Study objective

To study the difference between the vaginal microbiome of fertile women with IBD and healthy controls, as determined by lactobacillus dominance.

Study design

This study consists of a cross-sectional non-interventional design where a cohort of fertile woman with IBD and healthy controls will be asked to participate. They will be informed about the study during their routine check-up at the Erasmus MC at the outpatient clinic.

Study burden and risks

Patients and healthy volunteers who agree to participate in the study will be asked to provide a vaginal and fecal sample and fill out a questionnaire. 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
The subject signs and dates a written, informed consent form and any required privacy authorization prior to the initiation of any study procedures.
Participants are aged in the fertile phase, between 18 and 45 years.
Participants have a confirmed IBD diagnosis based on diagnostic criteria using clinical symptoms, endoscopic, radiological and histological results.
In the opinion of the investigator, the subject is capable of understanding, reading and speaking the Dutch language and complying with protocol requirements.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
Postmenopausal women.
Presence of active malignancy or dysplasia.
Pregnant and/or breastfeeding women.
Presence of active rotavirus or clostridium infection at start of study.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-08-2020
Enrollment:	83
Type:	Anticipated

Ethics review

Approved WMO

Date:	24-08-2020
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	NL72730.078.20