Inflammatory Bowel Disease Tracker

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

Summary

ID

NL-OMON46657

Source
ToetsingOnline

Brief title
IBD Tracker

Condition

- Gastrointestinal inflammatory conditions

Synonym
Inflammatory bowel disease - Crohn's disease or ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Center for Microbiome Informatics and Therapeutics, Massachusetts Institute of Technology
Source(s) of monetary or material Support: Grant van het MIT Center for Microbiome Informatics and Therapeutics

Intervention

Keyword: Genetics, Inflammatory bowel disease, Metabolome, Microbiome

Outcome measures

Primary outcome

Changes in the gut microbiome, metabolome (in stool, in blood, and in urine), and physiological biomarkers in correlation with patients* health or disease state over the 12-month study period. At the end of the 12-month study period, in all patients, we will have profiled numerous biomarkers, as well as tracked their general well-being and disease activity using the clinical disease activity scores (the Simple Clinical Colitis Activity Index for ulcerative colitis, or the Harvey Bradshaw Index for Crohn*s Disease).

Secondary outcome

NA

Study description

Background summary

Inflammatory Bowel Diseases (IBD) are chronic, incurable, life-long conditions characterized by disease episodes of relapsing inflammation of the intestinal tract. In the United States and Europe, two forms of IBD are most prevalent, ulcerative colitis and Crohn*s Disease. For both conditions, patients move between active and inactive disease with an unpredictable frequency. During periods of active disease (exacerbations), they suffer an array of symptoms including diarrhoea, faecal urgency, faecal incontinence, fever, fatigue, abdominal pain and cramping, that significantly negatively impact their quality of life and make it difficult for them to adhere to regular daily routines. The unpredictable nature of the disease course of IBD, the debilitating symptoms, and the necessity of using immunosuppressant medication result in a high burden of stress and an impaired quality of life for patients.

Study objective

The primary objective of this study is to identify biomarker fingerprints in patients with ulcerative colitis (UC) and Crohn*s disease (CD, that can indicate that an exacerbation has begun, although the patient still feels well. Ultimately, the appearance of this biomarker fingerprint could proactively trigger clinicians to change medications, or patients to change behaviours, perhaps avoiding or lessening the severity of the exacerbation.

Secondary objectives of our study are to better understand disease progression by characterising fluctuations in biomarkers from the microbiome, the metabolome (stool, blood and urine), and the physiological parameters that occur in individuals with ulcerative colitis and Crohn*s disease throughout a 12-month period, independent of whether they relapse or not. We will also determine how the biomarkers from the microbiome, the metabolome, and physiological parameters change in response to lifestyle and behavioral stimuli.

Study design

This is a prospective, observational study that will enroll a total of 100 patients at 2 sites: a cohort of 50 patients at Universitair Medisch Centrum Groningen (UMCG), The Netherlands, and another cohort of 50 patients at Massachusetts General Hospital (MGH), Boston, USA. At each site, we will enroll 25 eligible patients with ulcerative colitis, and 25 eligible patients with Crohn*s disease.

Study burden and risks

NA

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

• 18 years of age or older
• Be able to provide written informed consent prior to screening and to comply with the requirements of the study protocol
• Be able to read and write Dutch sufficiently
• Be able and comfortable to use new technology: the app and the smartwatch for 12 months
• Live / work in proximity of the UMCG to permit sample collection by UMCG clinical team
• Have had diagnosis of ulcerative colitis or Crohn*s Disease confirmed by a clinician for a disease duration of more than 2 years
• Have had quiescent ulcerative colitis or Crohn*s disease for the past 3 months or longer
• Have had most recent episode of active disease within past 24 months
• Have had a stable IBD medication regimen for at least 3 months

Exclusion criteria

• If female, is pregnant or is breast feeding, or intends to become pregnant within the 12-month study period
• Unable to provide informed consent or unwilling to participate
• Use of oral or intravenous antibiotics within 4 weeks prior to screening
• Evidence of untreated infection e.g. Clostridium diffiicile
• Confirmed diagnosis of other serious disease unrelated to ulcerative colitis or Crohn*s disease
• Current alcohol or drug abuse

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-06-2019
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	18-02-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	03-02-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL62559.042.18