DISCOvERIE: Development, dIagnosis, and prevention of gender-related Somatic and mental COmorbitiEs in iRritable bowel syndrome In Europe

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To provide an extensive clinical and psychosocial characterization of IBS patients with and without psychological and/or physical comorbidities, as well as of disease-controls without IBS, but with psychological and/or physical disease, and a…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational non invasive

Summary

ID

NL-OMON55114

Source
ToetsingOnline

Brief title
DISCOvERIE

Condition

- Gastrointestinal motility and defaecation conditions
- Muscle disorders
- Mood disorders and disturbances NEC

Synonym
Irritable bowel syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Horizon 2020

Intervention

Keyword: Irritable bowel syndrome

Outcome measures

Primary outcome

Study outcomes are divided into clinical characteristics (symptom scores for GI symptoms, other somatic symptoms, fatigue, psychological symptoms, nutrition, physical activity, and sleep pattern) and biological parameters (measurements from blood samples, fecal samples, colon biopsies, and a multi-sugar permeability test, and two stress assessments targeted at different pathophysiological mechanisms).

Primary study parameters are symptom scores from questionnaires:

- GI symptoms: IBS-SSS.

- Somatic symptoms other than GI symptoms: PHQ-15.

- Symptoms and severity of fibromyalgia: FIQ.

- Psychological symptoms: GAD-7, PHQ-9.

- Presence and severity of fatigue: MFI.

- Nutritional pattern: FFQ.

Secondary outcome

Symptom scores according to momentary assessment using ESM:

- GI symptoms

- Psychological symptoms

Environmental, social, and behavioral features according to momentary assessment using ESM.

Lifestyle factors registered by the humanITcare platform: physical activity, heart rate, sleep pattern.

Previous traumatic exposure: BTQ.

Parameters from biomaterials:

- Paracellular in vivo passage of large molecules (i.e. endotoxins, bacterial products): blood samples.
- GI permeability studies by multiple sugar test.
- Gut microbiota, including bacterial cell counting, metabolomic, transcriptomic and metagenomic analyses, cultivation of micro-organisms: fecal samplen, colon biopsies
- Dry weight percentage as an objective measure of stool consistency: fecal samples.
- Calprotectin as a measure of (low grade) inflammation: fecal samples.
- Whole genome SNP detection as a measure of genetic variants for phenotype association studies: blood samples.
- Molecular, cellular, and ultrastructural characterization of the intestinal mucosa, with a specific focus on intestinal barrier function, immune mucosal cell populations and enteric nerve fibers involved in neuro-plastic changes, eosinophil and mast cell degranulation, cell-to-cell interaction, including association between immunocytes, the epithelium and nerve fibers, and molecular transcriptome/proteome profiling: colonic biopsies.

- Resting state functional connectivity, regional cerebral blood flow with

blood oxygen-dependent level (BOLD) and arterial spin labeling (ASL): fMRI scan

during MIST.

- Neural responses to psychosocial stress: fMRI scan during MIST.

- Subjective and cortisol responses to stress: during MAST.

Study description

Background summary

The etiology and pathophysiology of IBS are incompletely understood, which hampers adequate diagnosis, follow-up of disease course over time, evaluation of therapy efficacy, and the development of new effective treatments. This leads to reduced quality of life for affected individuals and, together with a high world-wide prevalence, an important burden on health care as well as high costs for society. Better understanding of IBS etiology and pathophysiology, and its relation to common comorbid psychological and physical disorders, is necessary in order to clear the way to novel (personalized) effective treatment options.

Study objective

To provide an extensive clinical and psychosocial characterization of IBS patients with and without psychological and/or physical comorbidities, as well as of disease-controls without IBS, but with psychological and/or physical disease, and a healthy control group without IBS and comorbid psychological/physical disease. This will form a basis for the evaluation of similarities and/or differences in underlying pathophysiology and clinical characteristics between the different groups in order to better understand IBS and its comorbidities in the context of pathophysiology, disease course, and treatment efficacy of currently available treatment options.

Study design

This project concerns a European multi-center prospective, longitudinal, case-control observational study with a total duration of 4 years, including measurements at baseline, after 1 year, and after 2 years.

Study burden and risks

This study does not involve any incapacitated or minority groups, and is considered a low-risk study. No treatments or investigational products are involved. The obligatory part of the study consists of completing digital questionnaires (at home), which will take about 0.5 hours, in addition to two visits to Maastricht University. In case subjects agree to also participate in additional assessments, the second visit will take somewhat longer, and subjects need to perform the additional measurements (depending on which assessments they decide to undergo). These include collecting blood and fecal samples, performing a multi-sugar permeability test by collecting 24-hour urine after ingestion of a multi-sugar drink, collecting data via an eHealth platform, and completing digital questionnaires using ESM (and collecting colonic biopsies during a colonoscopy already requested by their treating physician as part of clinical care). Participants will be asked to also perform similar assessments after 1 and 2 years of follow-up. Apart from these clinical assessment visits, two optional stress function assessment visits can be scheduled to assess brain function and neuroendocrine stress system function. No important health risks are considered. Subjects will not directly benefit from participation 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 IBS according to Rome IV criteria
- Aged 18 years or older
- Ability to understand written Dutch and speak the Dutch language

Exclusion criteria

- Any organic explanation for the abdominal complaints.
- A history of abdominal surgery, except for uncomplicated appendectomy, laparoscopic cholecystectomy, and hysterectomy.
- Participation in another clinical study interfering with study activities or study objectives of this study, 1 month prior to the screening visit and throughout the study.
- Other severe disease(s) such as malignancy, severe heart disease, kidney disease or neurological disease, interfering with study evaluations.
- Severe psychiatric disease, other than the comorbid conditions explicitly studied, with necessary additional psychopharmacotherapy or psychiatric intervention involving day-care/ inpatient treatment at start of study or during the study, especially a diagnosis of bipolar disorder, schizophrenia, autism spectrum disorder, schizoaffective disorder or organic psychiatric disorder (current OR lifetime).
- Previous history of drug or alcohol abuse 6 months prior to screening.
- Consumption of antibiotics 3 months prior to the baseline visit.
- Pregnant or lactating at the baseline visit.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-06-2021
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO

Date:	22-02-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	13-09-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL75159.068.20

Study results

Date completed: 28-05-2024

Summary results
Trial ended prematurely