Maastricht IBS Cohort: Phenotypical and genotypical characterization of patients with Irritable Bowel Syndrome

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Aim of the present study is to set up a large cohort of IBS patients in order to identify different disease characteristics as well as aetiological and pathophysiological factors in (sub)groups of patients with this heterogeneous disorder. Various...

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

Summary

ID

NL-OMON50635

Source
ToetsingOnline

Brief title
Maastricht IBS Cohort

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
Irritable bowel syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Interne Geneeskunde
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Genotype, IBS, Phenotype

Outcome measures

Primary outcome

Hypothesis:

Subgroups of IBS patients can be identified according to phenotypical and genotypical patterns

Primary objective:

- To set up a cohort of at least 1000 IBS patients and 400 healthy controls in order to identify different patient subgroups according to phenotypical and genotypical patterns

Secondary outcome

Secondary objective:

- To study the course of disease in different subgroups of IBS patients after 3 and 5 years.

- To set up a biobank for future translational studies on the pathophysiology and disease characteristics of IBS. The biobank includes serum, DNA, fecal and eventual biopsy samples

Endpoints:

- Patient characteristics (medical history, demographic and psycho-social factors)

- Symptom scores

- Food patterns

- Blood, faecal and biopsy markers related to inflammation, intestinal immune activation (innate defence) and neuro-hormonal regulatory mechanisms

- Markers in VOCs (volatile organic compounds)

- Visceral perception

- Intestinal permeability

- Diagnosis of Joint Hypermobility Syndrome (according to Brighton criteria (including Beighton score))*.

- Avoidant/Restrictive Food Intake Disorder

- Avoidance of foods and influence on abdominal complaints

- Preferences of treatment choices

Study description

Background summary

Irritable bowel syndrome (IBS) is a functional intestinal disorder characterized by abdominal pain or discomfort associated with altered bowel habits, without indications for an organic cause. Complaints often increase after a meal, especially if the meal is rich in fat, and are reduced by defecation.

The etiology of IBS is not yet clear and a single causal factor cannot be defined. Psychological and social factors, like anxiety and depression seem to play a role. Furthermore biological factors like bacterial overgrowth, a dysregulation of the brain-gut-axis (i.e. serotonin dysfunction), increase in gut permeability, previous acute gastroenteritis, low grade inflammation and an increase in the number of mast cells and T-lymphocytes in the gut mucosa have been associated with IBS.

Several twin studies and familial aggregation studies in IBS are consistent with either a genetic or social learning hypothesis, and it is possible that both play a role. The prospect of identifying a genetic cause for IBS may be very important, because it raises the possibility of confirming that IBS is a

disease entity and suggests new insight into the pathophysiology of the disorder, providing new targets for drug development.

A promising test to positively diagnose IBS is the assessment of visceral perception (rectal barostat). If such a test could support an anamnestic assumption of IBS, this may limit more invasive investigations.

Study objective

Aim of the present study is to set up a large cohort of IBS patients in order to identify different disease characteristics as well as aetiological and pathophysiological factors in (sub)groups of patients with this heterogeneous disorder. Various phenotypical and genotypical markers will be evaluated. For this purpose, blood and faecal samples as well as symptom questionnaires will be collected and visceral perception and intestinal permeability will be measured.
Therefore we will set up a biobank to collect human material for future studies that will focus on the pathophysiology and disease characteristics of IBS, especially biochemical, microbial and genetic factors. Consent will be asked to collect data from standard questionnaires, to store serum samples, DNA, stool, VOCs and, when endoscopy is performed for clinical reasons, also biopsy specimens.

Study design

The tests are divided in baseline and optional part. The study participants (IBS-patients and healthy volunteers) will be asked to participate in the baseline part of the study and to be contactes for follow-up measurements after 3 and 5 years.
Those participating will be asked separately to participate in the optional part of the study. If subjects are not willing to participate in the optional part, they still can participate in the study.

Baseline analyses for inclusion in the study:
1. Questionnaires on symptoms, patient characteristics and dietary habits
2. Symptom diary, 14 days
3. Faecal collection
4. Collection of blood
5. Collection of exhaled air
6. Short mobility examination

Optional tests:
7. Gut permeability test (1 day of urine collection after ingestion of sugar drink)
8. Rectal barostat
9. ESM (digitel questionnaires)

The following tests will be performed at home:
Gut permeability test (1 day), Symptom diary (2 weeks) and ESM (1 week).
The other test will be performed at the medical centre.

The following tests will be performed in case a colonoscopy, sigmoidoscopy, or gastroduodenoscopy for clinical reasons is indicated and requested by the physician of the IBS patient:
10. Collection of biopsies

11. Side Study: 30 patients will be asked to collect all facel samples during one week, for microbiota analysis.

After 3 and 5 years, subjects will be invited to answer the questionnaires digitally again and to provide a blood, fecal and exhaled air sample.

For the follow-up assessment 2020, subjects will be invited to answer some digital questionnaires.

Study burden and risks

During blood sampling, the subjects will remain seated in a comfortable chair, with an adjustable back. No side effects are expected when sampling blood in this manner. Sometimes a bruise develops where the needle was inserted.

Barostat catheters used are commercially available and are safe for human use. The protocol used in this study is a clinically used, widely accepted protocol for testing visceral sensitivity and the same procedure was approved previously by the Medical Ethical Committee Maastricht (MEC 06-3-020). Introduction of the ballon can be uncomfortable. Inflation of the balloon can give discomfort, pain or urgency. In case a subjec reports intolerable pain, discomfort or urgency, the balloon will be deflated inmediately.

All ingredients of the gut permeability test beverage (lactulose, rhamnose and sucralose) are used in the food industry and are generally regarded as safe. No health risk is associated with the consumption of the test beverage and the subsequent collection of 24-h urine. Furthermore, the application of lactulose, rhamnose and sucralose, which will be used, has been approved previously by the Ethics committee (MEC 04-168).

The complication rate of endoscopy (including mucosal biopsy) is very low: 0.13% bleeding and 0.03% perforation.

Completing symptom questionnaires will last for 60 minutes. The short mobility examination will take up to 5 minutes.*

Contacts

Public
Selecteer

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

IBS patients:
1) IBS will be diagnosed according to the Rome III criteria:
Recurrent abdominal pain or discomfort at least 3 days per month in the last 3 months associated with 2 or more of the following:
* Improvement with defecation
* Onset associated with a change in frequency of stool
* Onset associated with a change in form (appearance) of stool
2) Based on the medical history and previous examination, no other causes for the abdominal complaints can be defined. , Healthy controls:
1) Age between 18 and 75 years

Exclusion criteria

IBS patients:
1) Abdominal surgery, except for uncomplicated appendectomy, laparoscopic cholecystectomy or hysterectomy. , Healthy controls:
1) Gastrointestinal disorders (current or in medical history) or current gastrointestinal complaints.
2) Abdominal surgery, except for uncomplicated appendectomy, laparoscopic cholecystectomy or hysterectomy.
3) Use of medication that can influence gastrointestinal motility or perception (like loperamide, butylscopolamine, psylliumsead (metamucil), duspatal, metoclopramide, domperidon, erytromycine and serotonin reuptake inhibitors), for at least 3 months before tests.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	1400
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2009

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-11-2009
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	01-03-2012
Application type:	Amendment
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	06-07-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-05-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-03-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-06-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	29-11-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	27-11-2020
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
ClinicalTrials.gov	NCT00775060
CCMO	NL24160.068.08