IBSQUtrition: Microbiota and Metabolite Profiles Linked to Severity in Irritable Bowel Syndrome

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To determine faecal microbiota composition and metabolite production (such as acetate, propionate and butyrate), and investigate differences between healthy controls and mild or severe patients IBS. Moreover, to investigate whether (clinical)...

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

Summary

ID

NL-OMON46540

Source
ToetsingOnline

Brief title
Microbiota profiling in IBS

Condition

- Gastrointestinal conditions NEC

Synonym
Spastic colon

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: 9 verschillende industriele bedrijven,Bioiberica,Darling,Ingredion,Roquette,Winclove

Intervention

Keyword: Irritable Bowel Syndrome, Metabolite, Microbiota, Severity

Outcome measures

Primary outcome

Primary endpoint of this study is microbiota composition and metabolite profiles, and the difference between groups and possible change after one month. These are assessed two faecal samples, which are analysed by 16S rRNA gene-based microbiota profiling.

Secondary outcome

Secondary parameters are dietary intake, Quality of Life, depression and anxiety scores, and stool consistency and frequency, which are assessed by validated questionnaires.

Study description

Background summary

Irritable Bowel Syndrome (IBS) is a gastro-intestinal disorder that strongly affects Quality of Life and impairs daily functioning. However, the aetiology and pathophysiology has been poorly understood. Studies suggest that intestinal microbiota in IBS is altered, however a general consensus remains elusive. This may be due to the large individual variation in microbiota and IBS symptoms, and the cross-sectional designs. Moreover, other factors like diet, wellbeing and metabolite profiles are often not taken into account. New evidence is suggesting that IBS severity may be an important factor in microbiota composition.

Study objective

To determine faecal microbiota composition and metabolite production (such as acetate, propionate and butyrate), and investigate differences between healthy controls and mild or severe patients IBS. Moreover, to investigate whether (clinical) parameters such as symptom severity fluctuated, and if these

fluctuations are associated with an alteration in faecal microbiota composition and metabolite production, one month after baseline, compared to healthy controls.

Study design

This study is an observational longitudinal study, with two data collection points (baseline and after one month).

Study burden and risks

This study has a relatively low burden and risk, since it is an observational study. Participants only have to visit the study site once (at the information event). All data collection will be done from home, and will be done twice, which include faecal samples online questionnaire.

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

For IBS patients:
- Adults, aged 18-65 years.
- IBS patients that meet the Rome IV criteria.
- In close proximity of Wageningen (max. 50 km), for practical reasons: collection of the faecal samples.
- Have an Body Mass Index (BMI) between 18.5 and 30 kg/m2.
- Signed informed consent.
- After T1, IBS severity will be checked using the IBS-SSS. Subjects will be included for follow-up at T2, when they have the most mild symptoms (n<=30) or most severe (n<=30) symptoms. ;Healthy controls: will be age (±5 years), gender and BMI (±1kg/m2) matched with IBS patients. Other criteria:
- Adults, aged 18-65 years.
- No history of IBS, as assessed by the Rome IV criteria.
- Has a score <75 from the IBS-SSS.
- Are age (±5 years), gender and Body Mass Index (±1 kg/m2) matched with IBS patients.
- In close proximity of Wageningen (max. 50 km), for practical reasons: collection of the faecal samples.
- Signed informed consent.

Exclusion criteria

For IBS patients:
Presence of gastro-intestinal diseases, such as celiac disease, Crohn*s disease, or Ulcerative colitis.
- Have a history of intestinal surgery that might interfere with study outcomes. This does not include an appendectomy or cholecystectomy.
- Presence of significant systemic diseases, such as diabetes mellitus, cancer, cardiovascular disease or respiratory disease.
- Female participants: currently pregnant or breast-feeding.
- Use of antibiotic treatment less than 3 months before start of the study and no use of antibiotics during the study.
- Are not participanting in another study during this study.
- Are an employee or student of the Division of Human Nutrition, Food and Biobased Research or Laboratory of Microbiologie, of Wageningen University & Research.
- Unwilling or unable to fulfil study criteria.
- If they are not selected in the most mild or most severe group at T1. ;For healthy controls:
- Presence of gastro-intestinal diseases, such as celiac disease, Crohn*s disease, or Ulcerative colitis.
- Have a history of intestinal surgery that might interfere with study outcomes. This does not include an appendectomy or cholecystectomy.

- Presence of significant systemic diseases, such as diabetes mellitus, cancer, cardiovascular disease or respiratory disease.
- Female subjects: currently pregnant or breast-feeding.
- Use of antibiotic treatment less than 3 months before start of the study.
- Are an employee of the Division of Human Nutrition, Food and Biobased Research or Laboratory of Microbiology, of Wageningen University & Research.
- Are subjects in another study during this study.
- Unwilling or unable to fulfil study criteria.

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):	06-09-2018
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO

Date:	03-05-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL64950.081.18