Nutrition to Relieve IBS symptoms by targeting the Microbiota

Published: 24-02-2021
Last updated: 08-04-2024

The primary objective is to determine the bifidogenic effects of a 4-week intervention with one of four dietary supplements (Chondroitin sulfate, NOVELOSE® 3490, and Pea Fiber, and Lactium®) in IBS patients. The secondary objective is to determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Food intolerance syndromes
Study type	Interventional

Summary

ID

NL-OMON51091

Source
ToetsingOnline

Brief title
NUTRIMI study

Condition

- Food intolerance syndromes

Synonym
Irritable Bowel Syndrome (IBS)

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support:
Ingredia,Ingredion,Nexira,Roquette,Topsector voor Kennis en Innovatie,Wecare probiotics

Intervention

Keyword: Fibres, IBS, Microbiota, Peptide

Outcome measures

Primary outcome

The main study parameter is the (relative) abundance of fecal Bifidobacterium.

Secondary outcome

The secondary study parameters are fecal microbiota composition, fecal SCFAs,

stool frequency and consistency, IBS-related complaints, and Quality of Life.

Study description

Background summary

Irritable Bowel Syndrome (IBS) is a functional gastrointestinal disorder that affects a large number of people. To date, no adequate treatment is available. This is partially due to the heterogeneity of the patients and the complicated pathology in which not all mechanisms are understood.
Based on results of in vitro screening within the IBSQUtrition project, we selected promising dietary supplements for validation of their potential beneficial effects on the microbiota of IBS patients.

Study objective

The primary objective is to determine the bifidogenic effects of a 4-week intervention with one of four dietary supplements (Chondroitin sulfate, NOVELOSE® 3490, and Pea Fiber, and Lactium®) in IBS patients. The secondary objective is to determine the effects this 4-week intervention on fecal microbiota profiles, SCFAs, IBS-related complaints, Quality of Life, and stool frequency and consistency in IBS patients.

Study design

A double-blind, randomized, placebo-controlled trial with five parallel arms

Intervention

4-week intervention period with five parallel arms: 1) Chondroitin sulfate, 2) NOVELOSE® 3490, 3) Pea Fiber, 4) Lactium®, and 5) Placebo supplement (Maltodextrin control), during which the study participants consume the respective supplement twice per day.

Study burden and risks

Study participants have to invest about 7.4 hours of their time in this study mainly to complete several questionnaires (short daily questionnaire, longer questionnaires at two occasions), which is conveniently all possible from home. At two occasions they have to collect stool (transported via courier to the research facility). They have to comply to consume a commercially available supplement twice daily for four weeks. There are limited risks for the study participants.

Contacts

Public
Wageningen Universiteit

Bornse Weilanden 9
Wageningen 6708 WG
NL
Scientific
Wageningen Universiteit

Bornse Weilanden 9
Wageningen 6708 WG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- IBS patients that meet the Rome IV criteria. This will be evaluated by the medical supervisor;
- Male and female adults, aged 18-65 years;
- Having a Body Mass Index (BMI) between 18.5 and 30 kg/m2;
- Willing to keep a stable dietary pattern throughout the study;
- Having a smartphone to fill out the daily questionnaires;

Exclusion criteria

- Having a gastro-intestinal disease, such as celiac disease, Crohn*s disease, or Ulcerative colitis;
- Having a history of intestinal surgery that might interfere with study outcomes. This does not include an appendectomy or cholecystectomy;
- Having a food allergy to milk protein or pulse protein;
- Presence of significant systemic diseases, such as diabetes mellitus, cancer, cardiovascular disease or respiratory disease;
- When applicable: currently pregnant or breastfeeding, or intending to become pregnant during the study, as this can affect stool patterns and wellbeing;
- Use of antibiotic treatment less than 3 months before start of the study and no use of antibiotics during the study;
- Use of prebiotics and/or probiotics (should be stopped 4 weeks before the start of the study) and infrequent use of other (fiber) supplements. Some supplements are allowed, but intake should be kept stable during the whole study period (Supplements will be judged by the medical supervisor MD Ben Witteman);
- Currently following a FODMAP-restricted diet;
- Use of medication that can interfere with the study outcomes, including anxiolytics (antidepressants are allowed), laxatives (Over-the-counter laxatives are allowed, but intake should be either stopped at least 4 weeks before the start of the study or kept stable during the complete study period), and codeine, as judged by the medical supervisor MD Ben Witteman;
- Participation in another clinical trial at the same time;
- Student or employee working at Food, Health and Consumer Research from Wageningen Food and Biobased Research;
- Alcohol intake * 2 (women) or * 4 (men) glasses of alcoholic beverages per day;
Abuse of illicit drugs
- being incapacitated

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-05-2021
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	11-05-2021
Application type:	Amendment
Review commission:	METC NedMec

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	NL75824.041.20
Other	volgt nog