

Nutrition to relieve IBS constipation

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

Summary

ID

NL-OMON50958

Source

ToetsingOnline

Brief title

NUTRIC study

Condition

- Food intolerance syndromes

Synonym

Irritable Bowel Syndrome

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-probiotica (Jiangsu)

Intervention

Keyword: IBS, nutrition, prebiotics, probiotics

Outcome measures

Primary outcome

The primary study parameter is stool pattern: stool frequency, stool consistency and stool volume.

Secondary outcome

The secondary study parameters are gastrointestinal complaints, Quality of Life, and HADS.

Study description

Background summary

Irritable Bowel Syndrome (IBS) is a disease 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 stool pattern in IBS-Constipation (IBS-C) patients.

Study objective

The primary objective is to determine the effects of a 4-week intervention with either a prebiotic supplement (Inavea pure acacia) or a probiotic supplement (Bifidobacterium lactis BLa80) on stool pattern (including stool frequency, consistency, and volume) in IBS-C patients. The secondary objective is to determine the effects of this 4-week intervention on GI complaints and quality of life in IBS-C patients.

Study design

A double-blind, randomized, placebo-controlled trial will be conducted with three parallel intervention arms

Intervention

A 4 week run-in period will be followed by a 4-week intervention period with three parallel arms: 1) prebiotic supplement (Inavea pure acacia), 2) probiotic supplement (B. lactis), and 3) 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 14.5 hours of their time in this study mainly to complete several questionnaires (short daily questionnaire, longer questionnaires at three occasions), which is conveniently all possible from home. They have to comply to consume a supplement twice daily for four weeks. At two time points, they have to collect their stool for five days. There are limited risks for the study participants.

Contacts

Public

Wageningen Universiteit

Bornse Weiland 9
Wageningen 6708 WG
NL

Scientific

Wageningen Universiteit

Bornse Weiland 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 + additional criteria specific for the constipation-predominant subtype.
- * Male and female adults, aged 18-70 years.
- * Have a Body Mass Index (BMI) between 18.5 and 30 kg/m² (self-reported).
- * Willing to keep a stable dietary pattern throughout the study.
- * Having a smartphone to fill out the daily questionnaires

Exclusion criteria

- * Having a disease that may interfere with the outcomes of this study, such as a known autonomic disorder, inflammatory bowel disease, coeliac disease, cancer, dialysis patients, chronic kidney failure, depression or hypothyroidism.
- * History of intestinal surgery (excluding appendectomy or cholecystectomy) or endometriosis.
- * Use of medication that can interfere with the study outcomes, including antidepressants (allowed when it is not subscribed for mental depression), codeine, and antibiotics, as judged by the medical supervisor MD Ben Witteman.
- * Use of prescribed laxatives. Over-the-counter laxatives are allowed, but intake should be either stopped before the start of the study or kept stable during the complete study period.
- * Use of prebiotics and/or probiotics (should be stopped 4 weeks before the start of the study) and infrequent use of other (fiber) supplements dedicated to bowel function improvements. 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).
- * If applicable: currently pregnant or breastfeeding, or intending to become pregnant during the study, as this can affect stool pattern and wellbeing.
- * Participation in another clinical trial at the same time.
- * Student or employee working at Food, Health and Consumer Research from Food and Biobased Research, or Department of Human Nutrition & Health, Wageningen University.
- * Alcohol intake * 2 (women) or * 4 (men) glasses of alcoholic beverages per day.
- * Abuse of illicit drugs, soft drugs, and nitrous oxide.
- * Smoking

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2021
Enrollment:	180
Type:	Actual

Ethics review

Approved WMO	
Date:	24-02-2021
Application type:	First submission
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	NL76449.041.21
Other	volgt nog