Postprandial Lipids in IBS and Nutritional Treatment

Published: 22-06-2021
Last updated: 04-04-2024

The primary objective of this study is to determine the effect of short-term Turmipure GOLD® supplementation on LPS translocation in IBS-D and IBS-M patients after a high-fat challenge.The secondary objective of this study is to determine the effect...

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

Summary

ID

NL-OMON50848

Source
ToetsingOnline

Brief title
PLINT study

Condition

- Gastrointestinal motility and defaecation conditions
- Food intolerance syndromes

Synonym
Irritable Bowel Syndrome, spastic colon

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Givaudan (Naturex),Ingredion,Nexira,Roquette,Topsector voor kennis en innovatie (TKI),WeCare probiotics

Intervention

Keyword: IBS, Lipids, Postprandial response, Turmeric

Outcome measures

Primary outcome

The primary study parameter is blood LPS levels.

Secondary outcome

The secondary study parameters are gastrointestinal complaints, and blood

levels of LPS-related biomarkers.

Study description

Background summary

Irritable Bowel Syndrome (IBS) is a disease that affects a large number of people. Adequate treatment is difficult, partially due to the heterogeneity of the patients and the complicated pathology in which not all mechanisms are understood. Based on literature and in vitro screening within the public private IBSQUtrition consortium project, we selected a turmeric supplement for in vivo validation of their potential beneficial effects on fat-induced intestinal barrier disruption as measured with LPS translocation in IBS patients with diarrhea.

Study objective

The primary objective of this study is to determine the effect of short-term Turmipure GOLD® supplementation on LPS translocation in IBS-D and IBS-M patients after a high-fat challenge.
The secondary objective of this study is to determine the effect of short-term Turmipure GOLD® supplementation on gastrointestinal complaints and LPS-related biomarkers in IBS-D and IBS-M patients after a high-fat challenge.

Study design

A double-blind, randomized, placebo-controlled cross-over trial.

Intervention

Three times a single dose (300mg) of Turmipure GOLD® and placebo.

Study burden and risks

Study participants have to invest about 16 hours of their time in this study. They will visit the research facility three times. On six occasions they have to consume one supplement or placebo capsule. The risks for participation are very small if not negligible. Consumption of high amounts of saturated fat may cause some gastro-intestinal discomfort. Blood sampling will be performed via a cannula and the insertion can be a bit painful and may cause a bruise. The amount of blood that is drawn from participants is relatively small (total amount collected = 132mL divided over two test days) and is therefore within acceptable limits.

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 + additional criteria specific for the diarrhea-predominant and mixed subtype: IBS-D and IBS-M
- Male and female adults, aged 18-70 years;
- Having a Body Mass Index (BMI) between 18.5 and 30 kg/m2;
- Willing to keep a stable dietary pattern throughout the study.

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 codeine and antibiotics, as judged by the medical supervisor.
* Use of anticoagulants (as curcumin has inhibitory effects on platelet aggregation).
* Use of prebiotics and/or probiotics (should be stopped 4 weeks before the start of the study) and infrequent use of other supplements dedicated to bowel function improvements. Some supplements are allowed (judged by medical supervisor MD Ben Witteman) but intake should be kept stable during the whole study period.
* Having swallowing problems with pills/capsules.
* Having a cow*s milk allergy or other food allergies.
* If applicable: currently pregnant or breastfeeding, or intending to become pregnant during the study.
* 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 * 14 (women) or * 28 (men) glasses of alcoholic beverages per week.
* Smoking and abuse of illicit drugs, soft drugs, and/or nitrous oxide.

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-11-2021
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	22-06-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	03-12-2021
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	NL75915.041.21
Other	volgt nog