# Postprandial Lipids in IBS and Nutritional Treatment

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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

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### 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

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

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

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### **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
Туре:	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

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