Randomized, Placebo-controlled Double-blind Cross-over Study to Evaluate the Effects of Oligofructose on Stool Frequency in Constipated subjects

Published: 04-04-2014
Last updated: 20-04-2024

To study the effect of fructo-oligosaccharides on functional constipation.

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

Summary

ID

NL-OMON40415

Source
ToetsingOnline

Brief title
TOMCAT: Trial on Oligofructose, Microbiota, and Constipation in Adults

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation, decreased frequency of defecation

Research involving
Human

Sponsors and support

Primary sponsor: Ingredion Incorporated

Source(s) of monetary or material Support: Ingredion Incorporated

Intervention

Keyword: Constipation, Microbiota, Oligofructose, Prebiotics

Outcome measures

Primary outcome

The primary parameter is the number of complete bowel movements per day in subjects with functional constipation according to Rome III criteria.

Secondary outcome

Secondary outcome parameters are Stool consistency (Bristol Stool Scale), Stool frequency, Severity of symptoms (Constipation Scoring System; CSS) and Quality of Life (Patient Assessment of Constipation Quality of Life; PAC-QoL).

Other study parameters:

Microbiota profile, fecal Bifidobacteria, Lactobacilli, Clostridia, E. coli and total bacterial count. Blood samples will be taken at baseline and end of treatment and stored for later analysis.

Study description

Background summary

The prevalence of functional constipation in Europe is estimated to be around 17%, making it a common disorder. The dietary non-digestible carbohydrates fructo-oligosaccharides have been shown to increase fecal bacterial mass and fermentation metabolites which might stimulate gut motility. Therefore, these dietary non-digestible carbohydrates might relieve functional constipation.

Study objective

To study the effect of fructo-oligosaccharides on functional constipation.

Study design

A 16-week, randomized, placebo-controlled, double-blind cross-over trial with a run-in period of 4 weeks, and two intervention periods of 4 weeks separated by a wash-out period of 4 weeks.
During the study, participants need to stop the use of laxatives and pre- or probiotic supplements.
Subjects will be stratified according to age, gender and number of bowel movements (both determined at screening). All participants will have one intervention period with one of the three treatment dosages, and one period with placebo. The participants will be randomly allocated to these groups.

Intervention

Placebo and one out of 3 dosages of short-chain fructo-oligosaccharide, NutraFlora® scFOS, (Degree of Polymerisation of 3-5; 2, 4 and 8 g/day) for 4 weeks. NutraFlora® scFOS will be given as oral chews.

Study burden and risks

Subjects will daily consume one out of 3 dosages of short-chain fructo-oligosaccharide, NutraFlora® scFOS, (DP 3-5; 2, 4 and 8 g/day) and placebo for 4 weeks. Supplementation of FOS can cause flatulence, belching, abdominal pain, and bloating at the onset of treatment. Symptoms are generally very mild at the lower doses tested in the present trial (less than 10 g daily). Subjects will be instructed to maintain their usual pattern of physical activity during the intervention periods. The subjects can maintain their habitual diet, with the exception of functional ingredients like pre- and probiotics and food products high in dietary fermentable fibers. Moreover, use of other laxatives is prohibited during the intervention periods. The subjects are asked to fill in an online diary during the intervention periods to record compliance to dietary guidelines and test product intake. Additionally, in week 1 , 4, 9 and 12 the subjects are asked to record the Bristol Stool Form Scale, Stool frequency and the CSS and PAC-QoL questionnaires. Additionally, subjects are asked to collect a faecal sample in week 1, 4, 9 and 12. Blood samples will be collected in week 1, 4, 9 and 12.

The subjects will not benefit directly from participation to the study. The risks associated with participation in this study are considered negligible. The main burden of this study consists of the intestinal complaints subjects will experience when not using laxatives and/or dietary fibres in the run-in period and placebo intervention periods. In addition, the burden will include the time involved in filling in the questionnaires, the blood collection (4

times) and the fecal sample collection (4 times).

Contacts

Public
Ingredion Incorporated

Finderne Ave 10
Bridgewater NJ 08807
US
Scientific
Ingredion Incorporated

Finderne Ave 10
Bridgewater NJ 08807
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age 18-75 yr
• Agree to study design (signed informed consent)
• At least two of the following symptoms >=25% of the defecations (ROME III) with criteria fulfilled for the last 3 months with symptom onset at least 6 months prior to study start:
o straining, lumpy or hard stool
o sensation of incomplete evacuation
o sensation of anorectal obstruction * blockage
o use of manual manoeuvres
o <3 bowel movements per week

• Availability of internet connection
• BMI 20-30
• Male and/or female
• Willingness to abstain from functional ingredients and such as probiotics, prebiotics, foods containing high amounts of fermentable fibers, and laxatives during the study.

Exclusion criteria

• Currently participating in another clinical trial
• Drug usage
• Excessive alcohol usage (>4 consumptions/day or >20 consumptions/week)
• Pregnancy or lactating
• Underlying disease of the GI-tract or previous laparotomy, except cholecystectomy and appendectomy.
• Use of antibiotics within 1 month prior to inclusion
• Vegetarians
• Weight loss >5 kg within 1 month prior to inclusion

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2014
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	04-04-2014
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	NL46640.081.14