The effect of galacto-oligosaccharides in constipated adults

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The objective of this study is to assess the effect of galacto-oligosaccharides (Biotis* GOS Omni powder) on the number of bowel movements in an adult population with self-reported constipation.

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

Summary

ID

NL-OMON49026

Source
ToetsingOnline

Brief title
TRANSIT study

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation, hard stool

Research involving
Human

Sponsors and support

Primary sponsor: FrieslandCampina Research
Source(s) of monetary or material Support: FrieslandCampina Research

Intervention

Keyword: Constipation, Oligosaccharides

Outcome measures

Primary outcome

Self-reported stool frequency, assessed weekly, in weekly in online

questionnaires

Secondary outcome

Self-reported stool consistency, assessed weekly in online questionnaires with

the Bristol 7-point stool scale.

Study description

Background summary

Constipation is one of the most common health impairments in the Western countries which can severely affect the individual*s quality of life and general well-being.
The current interventions for constipation include lifestyle and dietary modifications as well as pharmacological interventions with stool softeners, osmotic laxatives, and stimulant laxatives. Dietary modifications include an increased intake of fibre-rich fruits and vegetables together with a sufficient intake of water. In addition to those modifications, supplementation with dietary fibres may be considered to reduce symptoms of constipation.

FrieslandCampina has identified a specific galacto-oligosaccharide mixture that may affect stool characteristics and thereby may reduce symptoms of constipation. The aim of the present study is to investigate the effect of galacto-oligosaccharides in a dose of 5,5 gram or 11 gram per day on stool characteristics, microbiota composition and quality of life in adults with self-reported constipation.

Study objective

The objective of this study is to assess the effect of galacto-oligosaccharides (Biotis* GOS Omni powder) on the number of bowel movements in an adult population with self-reported constipation.

Study design

The TRANSIT study is a randomized, double-blind, placebo-controlled, parallel intervention study in 132 healthy adults with self-reported constipation. The study will include 3 arms; 5.5 gr and 11 gr galacto-oligosaccharides and a control product. After a baseline week, all subjects will be included in a 3,5 week intervention period, including a 4 day run-in period to get familiarized with the study product.

Intervention

The subjects, divided in 3 study groups (44 persons each) will consume either one of the interventions:

GOS: Biotis* GOS Omni powder, containing 15.1 gr powder with 11 gr active GOS (once per day)
GOS: Biotis* GOS Omni powder, containing 7.5 gr powder with 5.5 gr active GOS (once per day)
Control (placebo): 15.1 gr of Maltodextrin (once per day) maltodextrin.

Study burden and risks

Study subjects, using laxatives, will be asked to stop with the use since this will interfere with the study outcome. Stopping might induce intestinal complaints. When the complains become too painful the use of one enema/ week is allowed. If the enema does not result in relief within 24 hours the use of a laxative is allowed, the study subject will be taken out of the PP group of the study.

The intake of GOS might cause flatulence and bloating at the onset of the treatment. To reduce/ avoid this effect a run-in period of 4 days, in which the amount of the test product is gradually increased, is included in the study setup.

The subjects are asked to complete weekly questionnaires and collect a faecal sample at the start and at the end of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Males and females
Age * 18 years
BMI *18,5 and * 28,0 kg m2.
Healthy as assessed by the NIZO health questionnaire

Self-reported constipation according to the Rome IV criteria with the following criteria (for the last 3 months):
Fewer than three (3) bowel movements per week.
And one or more of the criteria below:
* Straining during at least 25% of all defecations
* Lumpy or hard stools (BSFS 1-2) in at least 25% of defecations,
* Sensation of incomplete evacuation for at least 25% of defecations,
* Sensation of anorectal obstruction/blockage for at least 25% of defecations,
* Manual manoeuvres to facilitate at least 25% of defecation (e.g., digital evacuation, support of the pelvic floor)
*Willingness to abstain from laxatives during the study

Exclusion criteria

- Major abdominal surgery interfering with GI function
- Major co-morbidities,such as diagnosed inflammatory bowel disease, diagnosed celiac disease, diagnosed diverticulitis, a history of gastrointestinal tumors and other unforeseen co-morbidities, that may have an impact on the study results (as decided by the medical investigator)
- Use of medication that may affect the results of the investigational product, such as physician prescribed laxatives, and medication that influences the motility of the GI tract
-Use of antibiotics 90 days before the start of the study
-Use of strict diets (Vegan diet, gluten free diet, or crash-diet with use of meal replacers)
-Self-reported lactose-intolerance
- Self reported cow's milk allergy
- Diagnosed diabetes
-Pregnant and lactating women
-Expected change in lifestyle within 14 days before and during the trial period (i.e. diet, physical activity, smoking, alcohol consumption and medication use)
-History of side effect with the use of prebiotic supplements
-Use of alcoholic beverages for men > 28 units/week and >4/day; for women: >21 units/week and >3/day

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-08-2020

Enrollment:	132
Type:	Actual

Ethics review

Approved WMO Date:	15-06-2020
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL73442.028.20