The effect of galacto-oligosaccharides in constipated adults

Gepubliceerd: 02-07-2020 Laatst bijgewerkt: 18-08-2022

After 3 weeks, number of bowel movements increased with at least 1 time per week more in the group receiving the high dose of GOS compared to the control group receiving maltodextrin.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23365

Bron
NTR

Verkorte titel
Transit

Aandoening

Constipation

Ondersteuning

Primaire sponsor: FrieslandCampina
Overige ondersteuning: Frieslandcampina

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Stool frequency

Toelichting onderzoek

Achtergrond van het onderzoek

The aim of the study is to investigate whether consumption of galacto-oligosaccharides could lead to improved gut comfort in 132 adults aged 18 years or older with self-reported constipation (3 groups of 44 people; 1 high dose galacto-oligossacharides, 1 low dose galacto-oligossacharides and 1 control group)

Doel van het onderzoek

After 3 weeks, number of bowel movements increased with at least 1 time per week more in the group receiving the high dose of GOS compared to the control group receiving maltodextrin.

Onderzoeksopzet

July 2020 start study. Participants will be included batch-wise (approximately 10 per week). One week for the intervention, stool frequency (with a diary) and stool consistency (with the Bristol Stool Form Scale), will be measured and after the intervention, on day 25, this will be repeated

Onderzoeksproduct en/of interventie

High dose of galacto-oligosaccharides, low dose of galacto-oligosaccharides and the control group receiving maltodextrin

Contactpersonen

Publiek

FrieslandCampina
Dominique ten Haaf

06-21686497

Wetenschappelijk

FrieslandCampina
Dominique ten Haaf

06-21686497

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Substantial:
• 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):
o Fewer than three bowel movements per week.
o And one or more of the criteria below:
straining during at least 25% of all defecations
lumpy or hard stools (Bristol Stool Form Scale 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 defaecaltion (e.g., digital evacuation, support of the pelvic floor)

Procedural:
• Ability to follow Dutch verbal and written instructions
• Availability of internet connection
• Signed informed consent
• Willing to accept disclosure of the financial benefit of participation in the study to the authorities concerned.
• Willing to accept use of all encoded data, including publication, and the confidential use and storage of all data for at least 15 years.
• Willing to comply with study procedures, including collection of stool samples and alcohol restriction of maximum 2 consumptions per day
• Willing to abstain from non-prescription laxatives (starting at least 2 weeks before the start of the baseline period)
• Willing to abstain from drugs use during the study

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Substantial:
• 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 protein 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

Procedural:
• Not having a general practitioner, not allowing disclosure of participation to the general practitioner or not allow to inform the general practitioner about abnormal results.
• Participation in any clinical trial including blood sampling and/or administration of substances starting 1 month prior to study start and during the entire study.
• Personnel of NIZO or FrieslandCampina, their partner and their first and second degree relatives.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	05-07-2020
Aantal proefpersonen:	132
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	02-07-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8758
Ander register	METC Brabant : METCP2022

Resultaten