The effect of galacto-oligosaccharides (GOS) or chicory fructo-oligosaccharides (FOS) versus a placebo on bowel habits in children with functional constipation.

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

Summary

ID

NL-OMON54813

Source
ToetsingOnline

Brief title
The Inside Study

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
constipation, functional constipation

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: FrieslandCampina,Sensus B.V.,TKI Agrifood

Intervention

Keyword: children, functional constipation, prebiotics

Outcome measures

Primary outcome

The primary outcome measure will be change in stool consistency.

Secondary outcome

Secondary outcomes includes stool frequency and stool consistency in number of

cases (%).

Study description

Background summary

Functional constipation (FC) in children is a common gastrointestinal (GI) disorder with a worldwide prevalence ranging from 0.7% to 29.6%. Complaints include infrequent bowel movement, painful defecation due to hard and/or large stools, faecal incontinence, and abdominal pain. Although the condition is rarely life-threatening, it strongly impairs quality of life. Fibres such as chicory fructo-oligosaccharides (FOS) and galacto-oligosaccharides (GOS) have been shown to relieve constipation symptoms in young adults and elderly. However, sufficient evidence is lacking linking additional fibre intake to improve symptoms in children with FC. We hypothesize that GOS and FOS might be able to relieve symptoms of constipation in young children as well, among which softening stools.

Study objective

In the present randomised double blind controlled study, we will study the effects of GOS or FOS vs a placebo on stool consistency. Other parameters to be investigated include stool frequency, stool consistency in number of cases (%), painful defecation, quality of life of the child, gastrointestinal symptoms, gut microbiome outcomes, faecal pH, dietary intake and, if age appropriate abdominal pain, and the number of times escape medication was used between groups.

Study design

Parallel study with three arms of duration one week run-in, 8 week placebo-controlled randomised double-blind intervention with a 4 week wash-out afterwards.

Intervention

Research subjects will receive either one spoon of 8.5mL of GOS, FOS or a placebo, which corresponds to 4,35 g GOS (6.3 g Vivinal GOS); 3,70 g FOS (4.0 g Frutalose®OFP) or 3,35 g maltodextrin (Roquette Glucidex®) per day added to foods or drinks for 8 weeks.

Study burden and risks

A significant body of scientific literature can be found which shows that inulin-type fructans including FOS from chicory roots are well-tolerated, including infants in human studies. United States Food and Drug Administration (US FDA) have confirmed chicory root derived inulin-type fructans as a safe ingredient through its formal review of Sensus* GRAS (Generally Recognized As Safe) documentation. As part of this formal review process, the FDA specifically reviewed documentation in two areas: chicory FOS production and whether or not chicory FOS contained allergens found in chicory and other inulin containing plants. No allergens were found in Sensus chicory root derived FOS at detectable levels. Daily doses of 0.612 g/100 ml chicory FOS are used in commercial Dutch and US infant formulae. Frutalose®OFP FOS is used in baby and adult food globally i.e. Europe, US and Asia.
For GOS many studies have been performed to substantiate safety and tolerance. Vivinal GOS is used world-wide as an ingredient in standard and premium infant formula, follow-on formulas, growing up milk and products for adults. GOS has been extensively tested in infant and adult studies all over the world [10-12]. Studies in infants showed that consumption of GOS up to 0.8g/100 ml is well-tolerated. Only in subjects with pre-existing allergies in the Southeast Asian region, a very limited number of Vivinal GOS related allergic reactions has been reported over the past few years. After completing extensive scientific research and safety studies, Vivinal GOS received GRAS approval for use in food and infant food in the USA by the FDA. Furthermore, the European Union Scientific Committee on Food accepted GOS in infant and follow-on formulas, and GOS is regulated in the EU Directive 2006/141. Both chicory FOS and GOS are well-established prebiotics.
Measurements during this study only involve non-invasive measurements, including filling out of a diary, questionnaires, a dietary assessment, and faecal sampling. Moreover, the prebiotic group might benefit from the intervention, resulting in a softer stool consistency.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)
Babies and toddlers (28 days-23 months)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria, as considered by a medical doctor:
- Written informed consent obtained from parents or guardians of toddlers meeting the eligibility criteria and those willing to comply with the requirements of the study
- Aged 1-6 years (12 to 72 months at the day of inclusion) (at least 25% 1-2 years of age and at least 25% 2-3 years of age)
- Children that meet the following (Rome IV criteria): must include 1 month of at least 2 of the following in infants up to 4 years of age:
1. 2 or fewer defecations per week
2. History of excessive stool retention
3. History of painful or hard bowel movements

4. History of large-diameter stools
5. Presence of a large fecal mass in the rectum
In toilet-trained children, the following additional criteria may be used:
6. At least 1 episode/week of incontinence after the acquisition of toileting skills
7. History of large-diameter stools that may obstruct the toilet

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Children who suffer from any other GI complaints than FC, known structural GI abnormalities, or previous GI surgery
- Any condition that would make it unsafe for the child to participate. This can include developmental delays associated with musculoskeletal or neurologic conditions affecting the gastrointestinal tract. Children with underlying cause of defecation disorder (for example: Hirschsprung*s disease, spina bifida occulta, cystic fibrosis, or gastrointestinal malformations).
- Children with clinically significant cardiac, vascular, liver, pulmonary, psychiatric disorders, severe renal insufficiency, human immunodeficiency virus, acquired immunodeficiency syndrome, hepatitis B or C or known abnormalities of haematology, urinalysis, or blood biochemistry, as checked by the inclusion questionnaire.
- Children who are lactose intolerant for whom it is expected that low doses of lactose could lead to diarrhoea or children that are allergic to cow*s milk (GOS is derived from cow*s milk)
- Children who are allergic to fish
- Use of antibiotics or breast-feeding 4 weeks prior to the study
- Other medicines or food supplements, which can influence defecation and gut microbiota 1 week prior to the study run-in period. This includes e.g. infant formula(IF), follow-on formula (FOF) and young child formula (YCF), or products with labelled pre-and probiotics in the previous week prior to the study run-in period.
- Children on other supplements/ medication that would affect bowel function e.g. fibre supplements, and pre-, pro- and synbiotics (excluding escape medication during the trial as mentioned in chapter 3 and 5.3) for the past week.
- Children that participate in another clinical trial.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-06-2020
Enrollment:	198
Type:	Actual

Ethics review

Approved WMO Date:	21-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-07-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-09-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-04-2023

Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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
ClinicalTrials.gov	NCT04282551
CCMO	NL70126.081.19