The effect of galacto-oligosaccharides (GOS) versus a placebo on defecation parameters and microbiota in healthy children with hard or lumpy stools

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

Summary

ID

NL-OMON54825

Source
ToetsingOnline

Brief title
The Inside Study II

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
difficulty with defecation, hard or lumpy stools

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: FrieslandCampina,TKI Agrifood

Intervention

Keyword: children, hard stools, 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

Firm, hard or lumpy stools can be problematic for young children and might come as a precursor of functional constipation in childhood. The cause of harder stools in childhood is incompletely understood. But it is likely that harder stools in childhood are linked to withholding behaviour of stools, a low fibre intake, and the gut microbiota composition. As hard stools may precede functional constipation, the aim of the study is to investigate the effect of GOS versus a placebo on defecation parameters and microbiota in healthy children with hard or lumpy stools, aged 1-6 years. We hypothesize that consumption of GOS results in softer stools and changes in microbiota.

Study objective

In the present randomised double blind controlled study, we will study the effects of GOS vs a placebo on stool consistency in children with hard or lumpy stools. 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.

Study design

Parallel study with two 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. For blindness dosage is based on spoon size, which corresponds to approximately 4,35 g GOS (6.3 g Vivinal® GOS powder) or 3,35 g maltodextrin (Roquette Glucidex®) per day added to foods or drinks for 8 weeks.

Study burden and risks

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 young child formulas and products for adults. GOS has been extensively tested in infant and adult studies all over the world. 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.

Contacts

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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 the researchers:
1. 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
2. Aged 1-6 years (12 to 72 months at the day of inclusion)
3. Hard or firm stools (score of 1 or 2 according to the mBSFS) for more than 50% of the defecations in the past month, as reported by parents and confirmed by the diary of the first week of the study.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Children who suffer from FC according to the Rome IV criteria: Must include 1 month of at least 2 of the following in infants and children up to 4 years of age:
o 2 or fewer defecations per week
o History of excessive stool retention
o History of painful or hard bowel movements
o History of large-diameter stools
o Presence of a large fecal mass in the rectum
In toilet-trained children, the following additional criteria may be used:
o At least 1 episode/week of incontinence after the acquisition of toileting skills
o History of large-diameter stools that may obstruct the toilet
- Children who suffer from GI complaints, 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 allergic to fish
- Use of antibiotics 4 weeks prior to the study run-in period.
- Children on other supplements/ medication that would affect bowel function 1 week prior to the study run-in. This includes e.g. breast milk, fibre supplements, pre-, pro-, and synbiotics, infant formula, follow on formula or, young child formula
- 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):	28-04-2021
Enrollment:	196
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-07-2021
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
Other	clinicaltrials.gov, NCT04295213
CCMO	NL70820.081.19