Children Use Prebiotics via Digital/Day-care recruiting

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56893

Source
ToetsingOnline

Brief title
CUPID

Condition

- Other condition

Synonym
difficulty passing stool, hard stools

Health condition

harde ontlasting

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Sensus B.V. (Royal Cosun)

Intervention

Keyword: Children, Prebiotics, Stool consistency

Outcome measures

Primary outcome

The primary outcome measure will be (change in) stool consistency.

Secondary outcome

Secondary outcomes include (change in) stool frequency and stool consistency in

number of cases (%). Tertiary outcomes include gastrointestinal symptoms,

quality of life, and gut microbiome outcomes.

Study description

Background summary

Stool frequency and consistency change as transition takes place from breast milk or infant formula to more solid foods. When stools become firm, hard or lumpy this might be a precursor of functional constipation in childhood. The cause of harder stools in childhood is incompletely understood. Harder stools may be linked to low fibre intake, withholding behaviour, due to various reasons, and the gut microbiota. As both persistent or hard stools can be a burden for children, this study aims to investigate the effect of chicory oligofructose (synonym fructooligosaccharides; FOS) versus a placebo on defecation parameters and intestinal microbiota composition in healthy children with hard stools aged 1 until 4 years (12 - 48 months). We hypothesise that consumption of the oligosaccharide, oligofructose, results in softer stools and changes in the intestinal microbiota.

Study objective

This randomised double-blind placebo-controlled study will investigate the effects of a oligofructose vs a placebo on (change in) stool consistency in

healthy children with hard stools. Other parameters to be investigated include (change in) stool frequency, stool consistency in number of cases (%), gastrointestinal symptoms, quality of life, and gut microbiota composition.

Study design

Parallel study with two arms, placebo-controlled, randomised, double-blind intervention, with a run-in and wash-out period.

Intervention

Subjects will receive a can of Frutalose® OFP oligofructose or a placebo Roquette Glucidex Premium IT19 maltodextrin. Cans and scoops will look similar to ensure blinding. The scoop will be used to add the study product to foods or drinks for the duration of the intervention period (6 weeks).

Study burden and risks

A significant body of scientific literature can be found which shows that inulin-type fructans including inulin and fructooligosaccharides (FOS) from chicory roots are well-tolerated, including infants in human studies. The United States Food and Drug Administration (US FDA) has confirmed chicory root-derived inulin-type fructans as a safe ingredient through its formal review of Sensus* GRAS (Generally Recognized As Safe) documentation. No allergens were found in Sensus chicory root-derived inulin or FOS at detectable levels. Inulin/FOS are used in baby and adult food globally i.e., Europe, US and Asia.
Measurements during this study only involve non-invasive measurements, including the modified Bristol Stool Form Scale (mBSFS), the Infant Toddler Quality of Life Questionnaire (ITQOL), faecal sampling and filling out a diary. 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

1. Aged 1-4 years old (12 - 48 months at the day of inclusion).
2. Hard stools (score of 1 or 2 according to the mBSFS) for most (i.e. more than 50%) of the defecations in the past month, as reported by the parents.
3. Written informed consent was obtained from both parents or guardians of toddlers meeting the eligibility criteria and those willing to comply with the requirements of the study.

Exclusion criteria

1. Children diagnosed with functional constipation or have a history of large-diameter stools that may obstruct the toilet.
2. Children who are diagnosed with gastrointestinal (GI) disorders or known structural GI abnormalities, or previous GI surgery.
3. Children on a vegetarian/vegan diet.
4. Use of antibiotics or laxatives 4 weeks prior to the study run-in period.
5. Children on other supplements/medication that would affect bowel functioning one week prior to the study run in. This includes e.g., breast milk, fibre supplements, pre-, pro-, and synbiotics; also infant-, follow-on-, or young child formula with prebiotics, probiotics or synbiotics; alternative formula without pre-, pro-, and synbiotics will be offered.
6. 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:	Pending
Start date (anticipated):	01-02-2024
Enrollment:	120
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	24-07-2024
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL82995.068.22