Impact of galacto-oligosaccharides on the intestinal microbial composition and -activity: a proof of concept study

Published: 05-06-2019
Last updated: 04-07-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON52662

Source
ToetsingOnline

Brief title
Galacto-oligosaccharides and Intestinal Activity / GAIA study

Condition

- Gastrointestinal conditions NEC

Synonym
Gastrointestinal symptoms

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: NWO

Intervention

Keyword: Galacto-oligosaccharides, Microbial composition and -activity, Proof of concept, Proximal colon

Outcome measures

Primary outcome

Microbial composition and activity

Secondary outcome

Digestive parameters / side effects

Metabolite-related genes

Study description

Background summary

The intestines contain large amounts of bacteria which contribute to well functioning digestive system. Bacteria are involved in breakdown of nutrients, but also in the immune system of the human body. Previous research has been shown that dietary fibers are able to moduclate the composition of the microbiota, especially in the large intestine, thereby inducing additional health effects. In this study we will further investigate the effects of galacto-oligosaccharides (GOS), a dietary fiber which is naturally present in milk and for example is added to infant food.

Study objective

We would like to investigate whether GOS benefically alters the microbiota composition and -activity of the colon (not only faeces as done previously). This has not been done before by performing colonoscopies in a physiological condition and therefore highly relevant to compare with microbiota composition and -activity in faeces. This information will gain more insights in the working mechanism of this specific dietary fiber. In case study results will be positive, this may lead to the development of more and new health promoting foodproducts.

Study design

The study conforms to a randomized, double-blind and placebo-controlled design

including two parallel arms

Intervention

Subjects will be randomized into one of the two groups. One group will receive 7.2 grams of GOS supplements tree times daily for four weeks. A second group will receive 7.2 grams of placebo supplements three times daily for four weeks.

Study burden and risks

There are burdens volunteers can experience during this study.
- After the screening visit, participants will have to visit the Maastricht University Medical Centre+ two times. In total, a participant will spend approximately six hours at the university facility.
- They will have to take GOS or placebo products three times daily for a time period of four weeks; the products used have been proven to be safe for human use.
- During the two colonoscopies, colonic luminal content and biopsy specimens will be collected, under sedation and after performing a standard enema. In subjects undergoing colonoscopy there is a very small risk of bowel perforation (0.0025%; report of the Gezondheidsraad). The risk of bleeding in symptomatic patients undergoing colonoscopy for medical reason is 0.24%. However, the risk of bleeding is associated with therapeutic interventions such as polypectomy. In this study no therapeutic interventions will be performed. The risk of complications is not increased when taking multiple biopsy specimens.
- During both test visits subjects will be asked to arrive fasted. During the same visits, body weight will be determind and subjects will bring a fecal sample, which will be collected and frozen at home.
- Moreover, questionnaires will have to be filled out at several occasions during this study. Besides we ask subjects to fill out a 3day food diary before handing in the first fecal sample. When collecting fecal samples later in the specific study period, we ask subjects to repeat the same food pattern and record this again in a diary.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL
Scientific

Universiteit Maastricht

Universiteitssingel 50
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

No gastrointestinal complaints
Age between 18 - 50 years
BMI between 20 - 30 kg/m2
Willing to be informed in case of unexpected findings

Exclusion criteria

Use of antibiotics within 90 days prior to the study
Use of anticoagulation medication (except Ascal)
Last colonoscopy within 90 days prior to the study
Inadequate or painful (self-reported) colonoscopy undergone in the past
American Society of Anesthesiologists (ASA) classification > 2

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2020
Enrollment:	10
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	05-06-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-06-2022
Application type:	Amendment
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
ClinicalTrials.gov	NCT04104360
CCMO	NL67736.068.18