Impact of galacto-oligosaccharides on microbial fermentation capacity and markers of frailty in adults and elderly

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

Summary

ID

NL-OMON45484

Source
ToetsingOnline

Brief title
GOS and microbial fermentation in aging

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: Aging, Galacto-oligosaccharides, Immune system, Microbial fermentation

Outcome measures

Primary outcome

Microbial composition and activity

Secondary outcome

Innate immune signaling and defence

Metabolite production

Digestive parameters / side effects

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 modulate the composition of the microbiota, especially in the large intestine, thereby inducing additional health effects. In this study, we will investigate the effects of galacto-oligosaccharide, a dietary fiber which is derived from milk, on microbial fermentation capacity and markers of frailty in adults and elderly.

Study objective

This study will be don to gain insights in the effects of the dietary fiber pectin on gut functioning and the immune system.
The information will gain more insights in the working mechanism of this specific dietary fiber. Further, we are especially
interested in possible different effects in healthy adults when compared to elderly people. In case study results will be
positive, this may lead to the development of more and new health promoting foodproducts. In case there will be different
effects in different age groups, this may lead to new foodproducts targeting one specific age group.

Study design

The study conforms to a randomized, double-blind and placebo-controlled design including two cross-over intervention periods

Intervention

Subjects will be randomized into one of the two intervention periods. One period subjects will receive 7.24 grams of Vivinal GOS supplements three times daily for four weeks. In the other period, subjects will receive 7.24 grams of placebo supplements three times daily for four weeks.

Study burden and risks

There are small burdens volunteers can experience during this study. After the screening visit, participants will have to visit the Maastricht Universitair Medisch Centrum+ six times. In total, a participant will spend approximately three hours at the university facility. They will have to take GOS or placebo supplements three times daily for a time period of eight weeks; the supplements used have been proven to be safe for human use. During four visits and spread over 12 weeks, a total of 76 mL blood (fasted) will be sampled by venepuncture via an evacuated tube system, which may lead to minor discomfort and/or a small hematoma at the site of puncture. During the same visits, exhaled air samples will be collected and subjects will bring a fecal sample which is collected at home. Moreover, questionnaires will have to be filled out at several occasions during this study. Besides we ask subjects to fill out a 3-day 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 40
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

No gastrointestinal complaints
Age between 25-50 years (and robust by citeria of Fried et al. 2001) and 70-85 years (and prefrail by criteria of Fried et al. 2001)
BMI between 20 and 30 kg/m2

Exclusion criteria

Use of antibiotics in the 90 days prior to the study
Use of laxatives within 14 days prior to the study
Pregnancy
Administration of probiotic or prebiotic supplements in the 14 days prior to the study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-03-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	01-03-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	31-05-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	20-12-2017
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
CCMO	NL59681.068.16
Other	Volgt, registratie in clinicaltrials.gov