The effect of lactose consumption in lactase non-persistent individuals on gut microbiota

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Ethical review	Approved WMO
Status	Completed
Health condition type	Gastrointestinal signs and symptoms
Study type	Interventional

Summary

ID

NL-OMON55015

Source
ToetsingOnline

Brief title
Lactastic

Condition

- Gastrointestinal signs and symptoms
- Food intolerance syndromes

Synonym
intestinal discomfort, lactose intolerance

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: FrieslandCampina (FC C.V.),Topsector voor

kennis en innovatie (TKI)

Intervention

Keyword: lactose, microbiota

Outcome measures

Primary outcome

The main study parameter is the change in fecal microbiota based on shotgun metagenomic sequencing upon repetitive consumption of (an increasing dose of) lactose.

Secondary outcome

The secondary study parameters are exhaled hydrogen with the hydrogen breath test, stool characteristics (such as pH, microbial lactase activity and dry weight), and GI comfort.

Study description

Background summary

Globally, about 70 percent of the adult population is lactase non-persistent (LNP), lacking the enzyme required for the digestion of lactose. It has been shown that most of the LNPers can still consume 12 grams (or more) of lactose in a single dose without suffering from any gastrointestinal (GI) discomfort. Dietary lactose might improve intolerance symptoms via the process of colonic adaptation. This study could provide insight into the threshold levels of repetitive dietary lactose needed to observe colonic adaptation and into what positive health effects the intake of lactose may have when colonic adaptation occurs.

Study objective

The primary objective of this study is to assess whether repetitive consumption of an increasing dose of dietary lactose in LNPers induces colonic microbial adaptation by a shift in microbiota composition and functional potential as measured with shotgun metagenomic sequencing. The secondary objective is to

assess whether repetitive consumption of an increasing dose of dietary lactose in LNPers results in decreased symptoms of lactose intolerance, by measurements such as hydrogen breath test, fecal lactase activity, and GI comfort.

Study design

This study will consist of a dose-response single-blinded intervention study, with three consecutive 4 week intervention periods.

Intervention

During the three consecutive intervention periods the study participants will consume twice a day 12 grams of sugar. This dose will consist of different ratios between beta-lactose and dextrose: twice a day respectively 3 grams, 6 grams, and 12 grams of lactose. This will result in a total daily lactose dose of 6, 12, and 24 grams, respectively.

Study burden and risks

The risks associated with participation are limited. The study participants can experience some GI discomfort, but the maximal intervention dose of lactose is chosen in such a way that expected lactose intolerance symptoms are limited. The study participants will have to visit the research facility in total 10 times (including information meeting) for screening, to pick-up the intervention product, to hand-in stool samples, and for two hydrogen breath tests. Study participants are furthermore requested to fill out daily GI comfort and stool pattern questionnaires via an app, and record their food intake with a 72-hour food diary at the beginning and ending of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

• Apparently healthy men and women
• Asian ethnicity
• Age between 18 and 50 years
• Body mass index (BMI) between 18.5 and 30 kg/m2
• LNP genotype
• Avoiding dietary lactose in habitual diet
• Regular stool frequency (on average at least once every two days)

Exclusion criteria

• Any metabolic, gastrointestinal, inflammatory or chronic disease (such as diabetes, anaemia, hepatitis, cardiovascular disease)
• History of gastro-intestinal surgery or having (serious) gastrointestinal discomfort
• Use of pre- and/or probiotics
• Use of medication that may influence the study results, such as laxatives and lactase peparations (e.g. Kerutab). Use of medication will be judged by the medical supervisor
• Having used antibiotics in the 6 months prior to the start of the study
• Reported slimming or medically prescribed diet
• Current smokers
• Alcohol intake >=2 (women) or >=4 (men) glasses of alcoholic beverages per day
• Pregnant or lactating (or having the wish to become pregnant during the study period, self-reported)
• Abuse of illicit drugs
• Having food allergies (no food intolerances)
• Insufficient proficiency in English to understand information brochure and

questionnaires
• Participation in another clinical trial at the same time
• Being an employee of the department Consumer Science & Health group of Wageningen Food & Biobased Research, Human Nutrition department of Wageningen University, or FrieslandCampina.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	17-08-2021
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	25-05-2021
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23633
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL74025.081.20
Other	Nog in bewerking

Study results

Date completed:	09-12-2021
Results posted:	16-09-2024
Actual enrolment:	25

First publication
16-09-2024