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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23633

Source
Nationaal Trial Register

Brief title
Lactastic

Health condition

Lactose intolerance

Sponsors and support

Primary sponsor: Wageningen Food & Biobased Research
Source(s) of monetary or material Support: Ministry of Economic Affairs, FC C.V.

Intervention

Outcome measures

Primary outcome

The change in fecal microbiota based on shotgun metagenomic sequencing

Secondary outcome

Exhaled hydrogen measured with the hydrogen breath test, stool characteristics 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.
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 of microbiota 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.
This study will consist of a dose-response single-blinded intervention study, with three consecutive 4 week intervention periods.
We aim to recruit 25 healthy Asian volunteers with a LNP genotype avoiding lactose in their habitual diet, 18-50yrs of age, BMI 18.5-30 kg/m2
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.
The main study parameter is the change in fecal microbiota based on shotgun metagenomic sequencing upon repetitive consumption of (an increasing dose of) lactose. The secondary study parameters are exhaled hydrogen measured with the hydrogen breath test, stool characteristics, and GI comfort.

Study objective

Repetitive consumption of an increasing dose of dietary lactose in LNPers induces colonic microbial adaptation and improves intolerance symptoms

Study design

Baseline, T=4, 8, and 12 weeks

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.

Contacts

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Eligibility criteria

Inclusion criteria

• Apparently healthy men and women (based on questionnaire)
• Asian ethnicity
• Age between 18 and 50 years
• Body mass index (BMI) between 18.5 and 30 kg/m2
• LNP genotype (based on buccal swab testing)
• Avoiding dietary lactose in habitual diet (self-reported via questionnaire)
• 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), judged by the medical doctor
• 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 preparations (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 (food intolerances are acceptable)
• 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 controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Yes

Plan description
Coded data will only be shared with the partners involved in the TKI project Lactastic after finishing the intervention as they will take part in sample analyses and data analyses. No personal data will be shared.

Ethics review

Positive opinion

Date:	03-06-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55015
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9516
CCMO	NL74025.081.20
OMON	NL-OMON55015

Study results