

Milk Digestion study

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To investigate whether there is a difference in gastric volume over time after ingestion of cow milk between lactose tolerant, habitual milk consumers reporting no GI symptoms and non-habitual milk consumers reporting GI symptoms after milk...

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

Summary

ID

NL-OMON27110

Source

Nationaal Trial Register

Brief title

MiDi

Condition

- Gastrointestinal signs and symptoms

Synonym

bloating discomfort pain nausea

Health condition

People experiencing gastro-intestinal discomfort after consumption of cow milk without being lactose intolerant or allergic to cow milk protein. Cow milk Digestion Gastric emptying rate Gastrointestinal discomfort Koemelk Vertering Maagledigingsnelheid Maag-darm klachten

Research involving

Human

Sponsors and support

Primary sponsor: Lactalis

Source(s) of monetary or material Support: Lactalis

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

Gastric emptying half-time based on gastric content (volume in mL) over time.

Secondary outcome

Subjective GI symptoms, wellbeing, thirst and appetite.

Study description

Background summary

MRI allows to follow digestion of food products in real-time and to visualize stomach contents in 3D in time providing information to determine gastric emptying rates. Some people report to experience abdominal discomfort when digesting cow milk without being lactose intolerant or allergic to cow milk proteins. Inter-person variability in digestion of milk proteins in the stomach en related differences in gastric emptying rate and intestinal digestion might be the origin of those complaints.

Study objective

To investigate whether there is a difference in gastric volume over time after ingestion of cow milk between lactose tolerant, habitual milk consumers reporting no GI symptoms and non-habitual milk consumers reporting GI symptoms after milk consumption.

Study design

Two groups will be compared: habitual milk drinkers without GI symptoms, who consume at least 700 mL cow milk a week, and non-habitual milk drinkers with GI symptoms, who consume a maximum of 200 mL cow milk a week.

Intervention

A MRI session of approximately 1.5 h where the research subject will consume 250 mL cow's milk.

Study burden and risks

Each research subject will partake in a screening session consisting of a 4-h lactose breath test, and a MRI session of approximately 1.5 h where the research subject will consume 250 mL cow's milk. The cow's milk will be UHT processed and is, hence, considered eminently safe. Before and after consumption MRI scans are made to measure gastric content. These measurements are non-invasive and carry minimal risk. The burden of the screening session and measurement sessions is anticipated to most likely be related to possible mild abdominal discomfort and to mild fatigue and/or boredom. The latter will be counteracted by allowing the research subjects to read (during the screening) or to listen to the radio during the session (during screening and measurement sessions). The study is non-therapeutic to the research subjects.

Contacts

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Eligibility criteria

Age

Adults (18-64 years)
Adults (18-64 years)

Inclusion criteria

Drinking cow milk (maximum of 200ml/week for those who declare to not drink habitually and a minimum of 700ml/week for those who declare to drink cow milk habitually)

Reporting/not reporting GI discomfort after cow milk consumption (depending on study group)

Female

BMI: 18.5 - 30 kg/m²

Age: 18 - 60 years

Healthy (self-reported)

Need to be willing to be informed about incidental findings of pathology

Exclusion criteria

Having a history of medical or surgical events related to the GI tract that may give rise to GI complaints

Medical drug use that influences the GI tract's normal function, e.g. the motility, pH etc: among others use of proton pump inhibitors, antacids, anti-depressants etc.

Medical drug use that influence the GI tract's microbiota: antibiotic use within 1 months prior to the pre-study screenings day Mental status that is incompatible with the proper conduct of the study

Daily use of probiotics

Weekly use of laxatives

Lactose intolerance (medically diagnosed or tested with a lactose breath test in screening visit) and cow milk allergy

Reported unexplained weight loss or weight gain of > 5 kg in the month prior to screening

Reported slimming or medically prescribed diet

Reported vegan or macrobiotic life-style

Alcohol consumption of more than 14 glasses/week

Smoking more than 4 cigarettes a day

Not willing to give stool sample during the study

Being pregnant, having the intention to get pregnant, lactating or being under postmenopausal hormonal treatment

Not having a general practitioner

Having a contra-indication to MRI scanning

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2018
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date: 05-10-2018
Application type: First submission
Review commission: METC Oost-Nederland

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Study registrations

Followed up by the following (possibly more current) registration

ID: 46025
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7316
NTR-old	NTR7531
CCMO	NL66536.081.18
OMON	NL-OMON46025

Study results