Investigating gastric emptying rate of cow milk by means of MRI in people that either do or do not experience gastrointestinal discomfort after milk ingestion.

Published: 01-10-2018
Last updated: 15-05-2024

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	Other condition
Study type	Interventional

Summary

ID

NL-OMON46025

Source
ToetsingOnline

Brief title
Milk DIgestion study (MiDi study)

Condition

- Other condition

Synonym
Difference in gastric digestion of cow milk between people who do or do not experience abdominal discomfort

Health condition

fysiologie

Research involving
Human

Sponsors and support

Primary sponsor: Wageningen Universiteit
Source(s) of monetary or material Support: Lactalis

Intervention

Keyword: Cow milk, Digestion, Gastric emptying rate, Gastrointestinal discomfort

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

Ingestion of 250 mL cow 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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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-11-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	01-10-2018
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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: 27110

Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66536.081.18
OMON	NL-OMON27110