Investigating gastric emptying of cow milk in healthy subjects, who either do or do not experience gastro-intestinal discomfort after cow milk ingestion

Published: 03-05-2018
Last updated: 11-04-2024

To investigate whethere there is a difference in gastric emptying (emptying half-time t50) after ingestion of cow milk between lactose tolerant, habitual milk consumers reporting no gastro-intestinal symptoms and non-habitual milk consumers...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46478

Source
ToetsingOnline

Brief title
MIlk DIgestion study (MiDi study)

Condition

- Other condition

Synonym
Difference in gastric digestion between cow milk consumers that 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, Gastro-intestinal discomfort

Outcome measures

Primary outcome

Gastric emptying half-time (t50) derived from gastric content (volume in mL)

over time.

Secondary outcome

Subjective GI symptoms, thirst and appetite.

Study description

Background summary

Some people report gastro-intestinal discomfort after the ingestion of milk without being lactose intolerant or being allergic to milk. It is hypothesised that interpersonal differences such as proteolytic activity and related different gastric emptying pattern are the underlying cause for the experienced symptoms.

Study objective

To investigate whethere there is a difference in gastric emptying (emptying half-time t50) after ingestion of cow milk between lactose tolerant, habitual milk consumers reporting no gastro-intestinal symptoms and non-habitual milk consumers reporting gastro-intestinal symptoms after cow milk consumption.

Study design

Two groups, habitual milk drinkers without gastro-intestinal symptoms, who

consume at least 700ml cow milk per week, and non-habitual milk drinkers with gastro-intetstinal symptoms, who consume a maximum of 200ml cow milk per week.

Intervention

Ingestion of 250ml cow milk.

Study burden and risks

Each research subject will partake in one screening session of a 4 hours lactose breath test, and in one MRI session of approximately 1.5 hours where the research subject will consume 250ml 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 one 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

Public
Wageningen Universiteit

Stippeneng 4
Wageningen 6708
NL
Scientific
Wageningen Universiteit

Stippeneng 4
Wageningen 6708
NL

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 milk habitually and a minimum of 700ml/week for those who declare to drink milk habitually)
Do report/do not report GI discomfort after milk consumption (depending on study group)
Not lactose intolerant (tested with lactose breath test)
Female
BMI:18.5 * 30 kg/m2
Age: 18 - 60 years
Healthy (self-reported)
Having given informed consent
Need to be willing to be informed about incidential 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 microbiom: antibiotic use within 1 months prior to the pre-study screenings day
Daily consumption of probiotics
Weekly use of laxatives
Lactose intolerance (medically diagnosed) and cow milk allergy
Reported unexplained weight loss or weight gain of > 5 kg in the month
Reported slimming or medically prescribed diet, vegan or macrobiotic life-style
Alcohol consumption of more than 14 glasses/week
Smoking more than 4 cigarettes a day
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:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Not approved

Date:	03-05-2018
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

No registrations found.

In other registers

Register	ID
CCMO	NL65385.081.18