Digestion and absorption of coagulated casein

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To compare gastrointestinal digestion (gastric emptying and postprandial amino acids dynamics) between two dairy-based drinks containing casein and matched on macronutrient composition but differing in mineral composition.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON20073

Source
Nationaal Trial Register

Brief title
CasCo

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
'gastric emptying' 'amino acid absorption'

Health condition
Healthy males - there was no health condition

Research involving
Human

Sponsors and support

Primary sponsor: FrieslandCampina
Source(s) of monetary or material Support: FrieslandCampina

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

1. Postprandial plasma amino-acid concentrations 2. Gastric emptying rate

Secondary outcome

1. Postprandial glucose and insulin levels 2. Gastric layer formation and other product instabilities if visible 3. Fullness, bloating, nausea ratings obtained after each MRI measurement

Study description

Background summary
The degree of casein coagulation in the stomach can affect the dynamics of gastric protein digestion, stomach emptying and subsequent intestinal digestion and absorption of amino-acids. Previous studies (predominantly in vitro) suggest that casein coagulation is affected by several factors including processing-induced protein modifications, overall product composition (including mineral composition) and variations in gastric acidification and protease secretion. Particularly for the effect of product mineral composition on casein coagulation in vivo studies are lacking.

Study objective
To compare gastrointestinal digestion (gastric emptying and postprandial amino acids dynamics) between two dairy-based drinks containing casein and matched on macronutrient composition but differing in mineral composition.

Study design
Randomized cross-over study with two treatments

Intervention
Two 600ml milks containing casein and with similar macronutrient composition but differing in mineral composition.

Study burden and risks
The risks associated with participation are negligible, as both phlebotomy and MRI are eminently safe medical techniques, and the stimuli consist of normally consumed food products. The burden associated with participation consists of two visits, which both require an overnight fast, 13 blood draws (10 mL per draw, totalling 80 mL) and multiple MRI scans

over the period of 1 hours. These

may all cause minimal discomfort. These is no benefit to participation for the participants, the group is only related insofar as they are healthy males.

Contacts

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Eligibility criteria

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

Inclusion criteria

• Male • Age 18 – 55 y • Healthy • Normal-weight (BMI 18.5 – 25)

Exclusion criteria

• Cow milk allergy or intolerance (self-reported) • Lactose intolerance (self-reported) • Gastric disorders or regular gastric complaints, heart burn for example • Use of proton pump inhibitors or other medication which alters the normal functioning of the stomach, such as: o 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. o Medical drug use that influence the GI tract's microbiota: antibiotic use within 1 months prior to the pre-study screenings day • Use of recreational drugs within 1 month prior to the pre-study screenings day • Alcohol consumption of more than 14 glasses/week • Being vegan • Participating in other research • Smoking • Having given a blood donation in the past 2 months • Having a contra-indication to MRI scanning (including, but not limited to): ■ Pacemakers and defibrillators ■ Intraorbital or intraocular metallic fragments ■

Ferromagnetic implants ■ Claustrofobia • Not having a general practitioner or unwillingness to share unexpected findings with the gen-eral practitioner

Study design

Design

Study phase:	N/A
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2020
Enrollment:	15
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Approved WMO

Date:	23-09-2020
Application type:	First submission
Review commission:	METC Oost-Nederland

Study registrations

Followed up by the following (possibly more current) registration

ID: 49160
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8959
Other	METC Wageningen : 71177
CCMO	NL71177.081.19
OMON	NL-OMON49160

Study results