Gastric casein coagulation and post prandial amino acid absorption: effect of the product matrix

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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	Other condition
Study type	Interventional

Summary

ID

NL-OMON49160

Source
ToetsingOnline

Brief title
Casco study

Condition

- Other condition

Synonym
normal digestion

Health condition

eiwitvertering bij gezonde mensen

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Amino acid absorption, Caseine, Coagulation, Gastric emptying

Outcome measures

Primary outcome

1. Postprandial plasma amino-acid concentrations

2. Gastric emptying rate

Secondary outcome

1. Glucose and insulin

2. Coagulation 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

The subjects will drink two 600ml dairy-based drinks containing casein and matched on 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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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Male
* 18 - 55 yr old
* In self-reported health
* BMI between 18,5 and 25kg/m2

Exclusion criteria

* Bovine milk allergy or intolerance (self-reported)
* Being vegan
* Lactose intolerance (self-reported)
* Disorders of the upper ingestive tract resulting in difficulties chewing/swallowing.
* Unexplained weight change
* Gastric disorders or regular gastric complaints, heart burn for example
* Use of proton pump inhibitors or other medication which alters the normal function-ing of the stomach
* Use of a 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.
* Use of a 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
* Smoking
* Having a contra-indication to MRI scanning (including, but not limited to):
* Pacemakers and defibrillators
* Intraorbital or intraocular metallic fragments
* Ferromagnetic implants
* Claustrofobic
* Not wanting information at unexpected findings

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

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

Ethics review

Approved WMO

Date:	17-09-2020
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: 20073
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL71177.081.19
Other	Zal parallel worden geregistreerd in Dutch Trial register
OMON	NL-OMON20073