

# 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.

|                              |                                                      |
|------------------------------|------------------------------------------------------|
| <b>Ethical review</b>        | Approved WMO                                         |
| <b>Status</b>                | Recruitment stopped                                  |
| <b>Health condition type</b> | Gastrointestinal motility and defaecation conditions |
| <b>Study type</b>            | Interventional                                       |

## Summary

### ID

NL-OMON20073

### Source

NTR

### 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. There is no benefit to participation for the participants, the group is only related insofar as they are healthy males.

## Contacts

### Public

Wageningen University and Research  
Elise van Eijnatten

0031642565543

### Scientific

Wageningen University and Research  
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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 general 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           |
|                    | p/a Radboudumc, huispost 628, |
|                    | Postbus 9101                  |

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024 361 3154

commissiemensgebondenonderzoek@radboudumc.nl

## 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