

MRI Exploration of Protein Digestion

Published: 04-04-2023

Last updated: 07-04-2024

The objective of this study is to investigate the feasibility of using MT and CEST MRI for in vivo monitoring of gastric protein digestion (coagulation and breakdown). This will be done by studying the effect of heating on gastric protein...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON53523

Source

ToetsingOnline

Brief title

MOVE

Condition

- Other condition

Synonym

NA (er wordt geen aandoening bestudeert)

Health condition

fysiologie van eiwit vertering

Research involving

Human

Sponsors and support

Primary sponsor: Wageningen Universiteit

Source(s) of monetary or material Support: TKI agri&food

Intervention

Keyword: Digestion, MRI, Protein, Stomach

Outcome measures

Primary outcome

1. Average MTR of the stomach content over time (a measure of semi-solid protein content)

Secondary outcome

1. Average CESTR of the stomach content over time (a measure of soluble protein/peptide content)

Study description

Background summary

Gastric digestion is the first step in the breakdown of dietary proteins, and is therefore important for further breakdown in the intestines and subsequent absorption of amino acids. Food processing, such as heating can modify the structure and digestibility of proteins. Digestion of dietary protein, and how this is affected by heating is often studied using in vitro digestion models that mimic the digestive tract of humans. However, outcomes from these models need to be verified using in vivo digestion data from humans. Such data can in turn be used to improve digestion models. Magnetic resonance imaging (MRI) may potentially be used to non-invasively monitor both in vivo and in vitro protein digestion, and hence, may bridge the gap between in vitro digestion models and real-life digestion physiology. Here we propose a feasibility study, in which we will evaluate whether MT and CEST MRI can be used for monitoring protein digestion in vivo in humans. Pasteurized and extensively heated skim milk (80 °C, 30 min) will be used as a test case to demonstrate the ability of these MRI methods to detect relevant differences in (protein) digestion.

Study objective

The objective of this study is to investigate the feasibility of using MT and CEST MRI for in vivo monitoring of gastric protein digestion (coagulation and breakdown).

This will be done by studying the effect of heating on gastric protein coagulation and breakdown using pasteurized and extensively heated milk as a test case.

Study design

Randomized cross-over study with two treatments (pasteurized and extensively heated skim milk). Participants will visit the hospital Gelderse Vallei two times in a fasted state. First, a baseline MRI scan will be made, following this, they have to drink 300 mL of milk and MRI scans will be made up until 95 min. In the two visit the participants will have to drink to two different types of milk products.

Study burden and risks

The risks associated with participation are low because MRI is a safe technique, and the test foods consist of commercial milk products. The burden associated with participation consists of two visits, which include an overnight fast and MRI scans for 95 mins. These may all cause minimal discomfort. There is no benefit of participation for the participants. The study will be performed with healthy participants.

Contacts

Public

Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL

Scientific

Wageningen Universiteit

Stippeneng 4
Wageningen 6708WE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

18-45 years old

Apparently healthy

Normal weight (BMI 18.5-25 kg/m²)

Exclusion criteria

- Milk protein allergy or intolerance y (self-reported) • Lactose intolerance (self-reported) • Gastric disorders or regular (>once a week) gastric complaints such as heartburn • Use of medication which alters the normal functioning of the stomach, such as: - 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. • Being pregnant, lactating or planning on becoming pregnant during the study • Use of recreational drugs within one week prior to the test day (marihuana, XTC, GHB, helium) • Alcohol consumption of more than 7 glasses/per week • Smoking (>2 cigarettes a week) • Having gained or lost more than 5 kg weight in the last month. • Participating in other biomedical research during the study period • Having a contra-indication to MRI scanning (including, but not limited to): - Intraorbital or intraocular metallic fragments - Ferromagnetic implants - Claustrofobia (self-reported) • Unwillingness to be referred to my general practitioner in case of a chance finding of pathology • Being an employee or thesis student of the Division of Human Nutrition and Health or the Laboratory of Biophysics at Wageningen University.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2023

Enrollment: 12

Type: Anticipated

Ethics review

Approved WMO

Date: 04-04-2023

Application type: First submission

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date: 21-06-2023

Application type: Amendment

Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL83133.091.23
Other	tbd