Gastric digestion and postprandial amino acid absorption of pea protein: effect of heat treatment and viscosity

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55330

Source
ToetsingOnline

Brief title
Protein Transition 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: Ministerie van OC&W

Intervention

Keyword: Amino acid absorption, Gastric emptying

Outcome measures

Primary outcome

Gastric content volume over time, postprandial plasma amino-acid

concentrations.

Secondary outcome

Intra-gastric processes (coagulation, emulsion stability), MRI markers (T2, MT)

Study description

Background summary

Due to global population growth and environmental constraints, the demand for food proteins from sustainable sources is rapidly growing. The quickly expanding field of plant-based food, generally uses protein concentrates or isolates as protein source. It is not clear yet to what extent heat treatment and structure affects their digestibility in vivo. Magnetic resonance imaging (MRI) is a promising research tool to assess such protein food characteristics in vivo.

Study objective

The specific objective of this study is to compare gastrointestinal digestion (gastric content volume changes and postprandial amino acids dynamics) between pea-protein based foods with different heat treatments and viscosity. The overarching objective of this study is to demonstrate the utility of MRI as a research tool for monitoring protein digestion.

Study design

Randomized, balanced cross-over study with three treatments.

Intervention

Participants will ingest three 400-mL test foods containing 20 g pea protein:
- Protein in suspension: 5% (5 g/100g) protein suspension unheated
- Protein in suspension: 5% (5 g/100g) protein suspension heated at 90°C
- Protein gel (representing the food matrix): 25% pea protein isolate gel, prepared via heating at 90°C
Gastric content volume changes and appetite ratings will be measured at baseline and every ten minutes postprandial up until 90 minutes. Baseline and postprandial plasma amino-acid concentrations will be measured up to 5 hours postprandial.

Study burden and risks

The risks associated with participation are low, as both phlebotomy and MRI are eminently safe techniques, and the test foods consist of food grade ingredients. The burden associated with participation consists of three visits after an overnight fast, 10 blood draws (totalling 123 mL) and multiple MRI scans over a period of 5 hours. These may all cause minimal discomfort. There is no benefit of participation for the participants. The study must be performed in 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

• Pea protein allergy (self-reported)
• Disorders of the upper ingestive tract resulting in difficulties chewing/swallowing.
• Unexplained weight change >5 kg in the month within 1 month prior to the pre-study screeningsday
• 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
• 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 (>2 sigarettes a week)
• 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
• Use of protein supplements during the study
• Following a medical diet

• Being an employee or student of the Division of Human Nutrition and health
•Having donated blood in the two months preceding the first visit
•Hb value below 8.4 mmol/L (as measured with finger-prick method)

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):	05-08-2021
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	13-04-2021
Application type:	First submission
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	NL74440.081.20
Other	Zal parallel worden geregistreerd in Dutch Trial register