Personal protein digestion variability

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Primary Objective: To quantify the variation in post-prandial plasma AA profiles between (and within) individuals after consumption of a poorly digestible plant protein source (lucerne).
Secondary Objective: To compare the variation in postprandial...

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

Summary

ID

NL-OMON51132

Source
ToetsingOnline

Brief title
Personal protein digestion variability

Condition

- Other condition

Synonym
protein digestion

Health condition

opname van eiwitten

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 uptake, kinetics, personal variation, protein digestion

Outcome measures

Primary outcome

The main study parameter is AA uptake kinetics e.g. the appearance of free amino acids in blood samples collected before and after consumption. We will determine and quantify between, and within-subject variability.

Secondary outcome

GI complaints via questionnaire

Study description

Background summary

There is currently no information on personal protein digestion variability. We recently performed a human intervention study on protein digestibility and absorption and observed that postprandial plasma amino acid (AA) profiles from an easy digestible animal protein were highly comparable among individuals. However, the same profiles from a less digestible plant-protein source (e.g. water lentil) showed a large variability among individuals. But in order to really speak of personalized digestibility, we must be able to demonstrate that the absorption rate of an individual is reproducible. Demonstrating personal differences in AA uptake kinetics will affect the way we value (new) protein sources. Determining and quantifying individual differences in digestion and absorption will allow us to better predict nutritional value of products and diets.

Study objective

Primary Objective: To quantify the variation in post-prandial plasma AA profiles between (and within) individuals after consumption of a poorly digestible plant protein source (lucerne). Secondary Objective: To compare the variation in postprandial AA profiles between a poorly digestible plant protein source and an easy digestible protein source (whey).

Study design

The study has a randomised, cross-over, controlled design. Two different treatments will be evaluated on five occasions with a washout period of minimum one week between the test days. We will provide participants two different protein sources; on three test days they will receive a poor-digestible protein source, on two test days an easily digestible protein source. On test days, research subjects will receive a product in the form of a protein drink, in randomised order. Blood will be collected via a catheter before and up-to five hours after protein consumption. Wellbeing, health complaints or other adverse effects will be collected via short questionnaires during each test day. After each test day gastrointestinal complaints are collected via an online questionnaire.

Intervention

Research subjects will receive two times an easy digestible protein source wey and three times a poorly digestible protein source lucerne. Both representing a 20g protein load.

Study burden and risks

This study is not related to a specific group. There are minor risks for the research subjects of this study. There are no direct benefits for the research subjects. The total amount of blood collected (430 ml) is spread over 6 weeks and we will exclude subjects with anaemia. Blood collection will therefore not be expected to cause any problems. Research subjects that will participate in the study will invest approximately 27 hours during the trial.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

* Apparently healthy men and women;
* Age between 18 and 40 years;
* Body mass index (BMI) between 18.5 and 30 kg/m2 ;
* Having veins suitable for blood sampling via a catheter (judged by study nurse/ medical doctor).

Exclusion criteria

* Any metabolic, gastrointestinal, inflammatory or chronic disease (such as diabetes, anaemia, hepatitis, cardiovascular disease),or having a condition or disease that may lead to an impaired immune system
* History of gastrointestinal surgery or having (serious) gastrointestinal complaints;
* History of liver dysfunction (cirrhosis, hepatitis) or liver surgery;
* Kidney dysfunction (self-reported);
* Any use of medication that may suppress the immune system, this will be judged by the medical supervisor;
* Use of medication that may influence the study results, such as gastric acid inhibitors, laxatives, stomach protectors and drugs that can affect intestinal motility, this will be judged by the medical supervisor;
* Anaemia (Hb values <7.5 mmol/L for women and <8.5 mmol/L for men);
* Reported slimming, medically prescribed or other extreme diets;
* Not willing to give up blood donation during the study;
* Current smokers;
* Alcohol intake *4 glasses of alcoholic beverages per day;
* Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported);
* Abuse of hard drugs;

* Not having a general practitioner;
* Participation in another clinical trial at the same time;
* Being an employee of the department Food, Health & Consumer Research of Wageningen Food & Biobased Research or the department of Nutrition and Health of Wageningen University

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):	26-10-2021
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO

Date:	29-07-2021
Application type:	First submission
Review commission:	METC NedMec

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	NL77937.041.21
Other	proces loopt