Dairy and Plant amino acid uptake - An explorative study

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

Summary

ID

NL-OMON53307

Source
ToetsingOnline

Brief title
DaPa study

Condition

- Other condition

Synonym
amino acid uptake kinetics, digestion and uptake

Health condition

opname van aminozuren

Research involving
Human

Sponsors and support

Primary sponsor: FrieslandCampina (FC C.V.)
Source(s) of monetary or material Support: FrieslandCampina (FC C.V.)

Intervention

Keyword: dairy protein, digestion, plant protein, uptake

Outcome measures

Primary outcome

The main study parameter is the postprandial profile (iAUC and peak Cmax) of total essential amino acids (TEAA) before and after consumption of pea, faba, casein, and whey.

Secondary outcome

Other study parameters include total and individual (essential) amino acid profiles (iAUC, peak Cmax, and Time-2-max) before and after consumption of pea, pea+methionine, pea+casein, faba, casein, and whey.

Study description

Background summary

To optimize the environmental sustainability, a protein transition to more plant-based protein sources is required. However, the protein quality of plant-based sources is lower than that of the dairy proteins casein and whey, which contain high levels of essential amino acids. The amino acid absorption characteristics of many plant-based proteins are unknown. Pea protein and faba protein could be very promising ingredients. Effect sizes obtained in this explorative study will gain valuable insights for future follow-up studies.

Study objective

The primary objective is to estimate differences in postprandial plasma total essential amino acids (TEAA) profiles after protein consumption, determined by appearance (profiling, iAUC and peak Cmax), between pea, faba, casein, and whey

in blood of healthy participants. The secondary objectives are 1) To estimate differences in postprandial plasma total and individual essential amino acids (individual EAA) profiles after protein consumption, determined by appearance (profiling, iAUC and peak Cmax), between casein, whey, faba, pea in blood of healthy participants, 2) To explore differences in effect sizes of postprandial plasma total (essential) amino acids (individual EAA, TEAA and TAA) profiles after protein consumption, determined by appearance (profiling, iAUC and peak Cmax), between casein, whey, faba, pea, pea-casein, and pea-methionine measured in blood of healthy participants, and 3) To estimate differences in postprandial plasma non-essential amino acids (individual AA) profiles after protein consumption, determined by appearance (profiling, iAUC and peak Cmax), between casein, whey, faba, pea, pea-casein, and pea-methionine measured in blood of healthy participants.

Study design

This explorative study has a randomized, cross-over, double-blind, controlled design.

Intervention

During each visit, research subjects will receive one of the six protein blends (whey protein, casein protein, faba protein, pea protein, pea protein + casein protein, pea protein + methionine) dissolved in water, representing a 20g protein load, in randomized order.

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. In this study, we will include healthy research subjects based on the study criteria and a health questionnaire. The total amount of blood collected (492ml) is spread over at least six weeks and we will exclude subjects with anemia. Blood collection will therefore not be expected to cause any problems. Research subjects that will participate in the study will invest approximately 49 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 >=18 and <=40 years;
• Body mass index (BMI) >=18.5 and <=30 kg/m2 ;
• Having veins suitable for blood sampling via a catheter (judged by study nurse/ medical doctor).

Exclusion criteria

• Any self-reported metabolic, gastrointestinal, inflammatory or chronic disease (such as anemia, diabetes, hepatitis, cardiovascular disease);
• Having a history of medical or surgical events that may significantly affect the study outcome, including: Inflammatory bowel disease, hepatitis, pancreatitis, ulcers, gastrointestinal or rectal bleeding; major gastrointestinal tract surgery such as gastrectomy, gastroenterostomy, or bowel resection; known or suspected gastrointestinal disorders, colon or GI tract cancer;
• Anaemia (Haemoglobin (Hb) values <7.5 mmol/L for women and <8.5 mmol/L for men), as assessed by finger prick blood during screening visit;
• Having a food allergy, cow*s milk protein, soy or bean protein allergy, favism (G6PD-deficiency), and/or lactose intolerance (self-reported);

• Use of glucose lowering drugs, insulin;
• Use of medication that may impact gastric emptying (e.g. gastric acid inhibitors or laxatives);
• Use of antibiotic treatment less than 1 month before start of the study and during the study;
• Use of anti-depressives as a treatment for depression;
• Use of protein supplements (must be stopped 1 week before the first test day);
• Reported weight loss or weight gain of > 3 kg in the month prior to pre-study screening, or intention to lose weight during the study period;
• Reporting to follow or having planned a slimming or medically prescribed diet.
• Not willing to keep a stable lifestyle during the study period;
• Recent blood donation (<1 month prior to test day 1 of the study) or not willing to stop donation during and 1 month after the study;
• Average alcohol intake >21 (women) or >28 (men) glasses of alcoholic beverages per week;
• Use of drugs;
• Current smokers;
• Pregnant, lactating or wishing to become pregnant in the period of the study (self-reported);
• Not having a general practitioner;
• Insufficient proficiency in Dutch to understand information brochure and questionnaires;
• Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before test day 1 of this study;
• Being an employee of the department Food, Health & Consumer Research of Wageningen Food & Biobased Research or FrieslandCampina R&D.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	05-04-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	21-03-2023
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	NL83659.091.23
Other	NL83659.091.23