PARROT-2: Postprandial plasma amino acid concentrations after dairy consumption

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To compare postprandial plasma amino acid concentrations over time after ingestion of a fixed amount of protein from different dairy products in healthy adults.

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

Summary

ID

NL-OMON44562

Source
ToetsingOnline

Brief title
PARROT-2

Condition

- Other condition

Synonym
protein absorption, protein digestion

Health condition

voedingsfysiologie in gezonde personen

Research involving
Human

Sponsors and support

Primary sponsor: FrieslandCampina Research
Source(s) of monetary or material Support: FrieslandCampina

Intervention

Keyword: amino acids, dairy, postprandial availability

Outcome measures

Primary outcome

Plasma amino acid concentrations before and at 13 time points (up till 5 hours)

after consumption of the dairy products

Secondary outcome

none

Study description

Background summary

Modulation of postprandial amino acid concentration is considered to be relevant in relation to muscle protein synthesis. A faster, higher postprandial peak of amino acid concentrations and in particular leucine after consumption of different types of proteins is associated with higher muscle protein synthesis. Many studies have been performed with isolated proteins and very few with actual consumer products. In a previous study (PARROT Study, June 2015 - June 2016) it is shown that blood amino acid concentrations vary after consumption of different dairy products with equal protein content and volume. This depends on the type of protein and the fat and energy content.

Study objective

To compare postprandial plasma amino acid concentrations over time after ingestion of a fixed amount of protein from different dairy products in healthy adults.

Study design

Randomized, single-blinded within-subject design (cross-over) in which 2 groups of 10 subjects both receive a different set of 6 different dairy products. Each subject within a group will receive all treatments on the same day of the week with a 1 week washout period between treatments.

Intervention

Single consumption of 6 different dairy products, depending on the study group, on 6 separate test days, in a portion size that contains 25 g of protein.

Study burden and risks

For this study healthy volunteers are selected. There is no direct benefit from participation, although volunteers will be reimbursed for their time investment. In total the subjects will visit the research lab 7 times (first visit is screening visit). There are restrictions with respect to eating, drinking, and physical activity during the test days and on the pre-test days. No restrictions or interventions apply on other days within the study period. There are no risks associated with the consumption of the test foods. Blood samples will be taken 14 times during each of these visits, during a 5 hour period. Blood will be drawn via an infuse, which will be set by an experienced research nurse.

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

- Age 18-65y
- BMI 18,5-30 kg/m2
- Non-smoking
- Healthy as assessed by the NIZO lifestyle and health questionnaire ("Verklaring leefgewoonten en
gezondheid") and according to the judgment of the study physician.
- Regular and normal Dutch eating habits as assessed by the NIZO lifestyle and health questionnaire (3 main meals per day)
- Veins suitable for cannulation (blood sampling)
- Voluntary participation
- Having given written informed consent
- Willing to comply with study procedures
- Accept use of all encoded data, including publication, and the confidential use and storage of all data for 15 years.
- Accept disclosure of the financial benefit of participation in the study to the authorities concerned

Exclusion criteria

- Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before Day 01 of this study
- 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
- Use of the following medication: glucose lowering drugs, insulin; medication that may impact gastric emptying (e.g. gastric acid inhibitors or laxatives)
- Diagnosed with diabetes, being treated for high blood glucose or increased fasting blood glucose (> 7 mmol/l in finger prick blood) as assessed during screening visit
- For men: Hb <8,5 mmol/l as assessed during screening visit; for women: Hb <7,5 mmol/l.

- Use of protein supplements
- Mental status that is incompatible with the proper conduct of the study
- A self-reported reported food allergy or sensitivity to dairy ingredients
- A self-reported allergy or sensitivity to acetaminophen
- Alcohol consumption > 28 units/week and 4/day
- Reported unexplained 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
- Reported slimming or medically prescribed diet
- Recent blood donation (<1 month prior to Day 01 of the study)
- Not willing or afraid to give up blood donation during the study
- Personnel of NIZO food research or Wageningen University, department of Human Nutrition, their partner and their first and second degree relatives
- Not having a general practitioner
- Not willing to accept information-transfer concerning participation in the study, or information regarding his health, like laboratory results and eventual adverse events to and from his general practitioner
-Pregnancy or lactating

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):	06-11-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-10-2017
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	05-11-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	04-12-2017
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	30-03-2018
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL62458.072.17