PARROT: Postprandial plasma amino acid concentrations after dairy consumption

Published: 25-08-2015 Last updated: 19-04-2024

Primary: To compare postprandial plasma amino acid concentrations after ingestion of a fixed amount of protein from different dairy products in elderly subjectsSecondary: To determine effects of a fixed amount of protein from different dairy...

Ethical review Approved WMO

Status Recruitment stopped

Health condition type Other condition **Study type** Interventional

Summary

ID

NL-OMON42406

Source

ToetsingOnline

Brief title

PARROT

Condition

Other condition

Synonym

protein absorption

Health condition

voedingsfysiologie in gezonde personen

Research involving

Human

Sponsors and support

Primary sponsor: FrieslandCampina Corporate 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 timepoints (up till 5 hours) after consumption of the dairy products

Secondary outcome

Plasma glucose and insulin concentrations at 9 out of the 14 time points.

Gastric emptying rate, based on 13CO2/12CO2 ratio in expired breath for up to 3

hours after meal consumption, and expressed as half-emptying time and lag

phase; and on postprandial acetaminophen concentrations in blood.

Subjective rating of appetite sensations (hunger, fullness, satiety, desire to eat and prospective food consumption).

Study description

Background summary

Elderly need higher amino acid concentrations than younger people to achieve similar 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.

Study objective

Primary: To compare postprandial plasma amino acid concentrations after ingestion of a fixed amount of protein from different dairy products in elderly subjects

Secondary: To determine effects of a fixed amount of protein from different dairy products on:

- Postprandial plasma glucose and insulin concentrations
- Gastric emptying rate of the liquid and solid phase of products
- Feelings of satiation/satiety

Study design

Single-blinded within-subject design (cross-over) with 10 subjects receiving each of 8 dairy products on separate test days, with one week washout period between treatments.

Intervention

Single consumption of 8 different dairy products, on 8 separate test days, in a portion size that contains 25g 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 9 times (first visit is screening visit). The study products consist of (mostly commercially available) dairy products, and dairy proteins. 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, nor with the use of the 13C tracer compounds or the breath sampling. The amount of paracetamol given with the foods (1000 mg) is similar to the recommended dosing for use as pain killer. 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. Exhaling breath into a sampling bag and completing the appetite scores are simple noninvasive procedures.

Contacts

Public

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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 over 60y
- BMI 21-30 kg/m2
- Non-smoking
- Healthy as assessed by the NIZO lifestyle and health questionnaire (*Verklaring leefgewoonten en gezondheid*).
- 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 empyting (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
- 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

Study design

Design

Study type: Interventional

Intervention model: Crossover

Allocation: Randomized controlled trial

Masking: Single blinded (masking used)

Control: Active

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 12-10-2015

Enrollment: 10

Type: Actual

Ethics review

Approved WMO

Date: 25-08-2015

Application type: First submission

Review commission: METC Wageningen Universiteit (Wageningen)

Approved WMO

Date: 15-09-2015
Application type: Amendment

Review commission: METC Wageningen Universiteit (Wageningen)

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 NL53912.081.15