The impact of the dietary protein matrix on post-prandial plasma amino acid responses in vivo in healthy young females

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To assess the impact of protein in a solid (bar) and liquid (drink) form on post-prandial amino acid responses in vivo in healthy young women.

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

Summary

ID

NL-OMON51160

Source
ToetsingOnline

Brief title
Drinks & Bites study

Condition

- Other condition

Synonym
Protein digestion; protein availability

Health condition

Eiwit vertering

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Food matrix, Protein availability, Protein digestion

Outcome measures

Primary outcome

To compare the impact of protein in a solid (bar) and liquid (drink) form on

post-prandial plasma amino acid concentration in vivo in healthy young females.

Secondary outcome

To compare the impact of protein in a solid (bar) and liquid (drink) form on

peak post-prandial amino acid concentration, overall post-prandial glucose and

insulin responses, and hunger, desire to eat, and fullness in vivo in healthy

young females.

Study description

Background summary

Protein intake is an essential stimulus for protein anabolism. Protein anabolism is modulated by plasma amino acid availability. Various aspects of the dietary protein matrix have been shown to impact the post-prandial amino acid response. However, it has not yet been investigated if ingestion of protein in a solid (bar) form results in different post-prandial amino acid responses when compared to a liquid (drink) form.

Study objective

To assess the impact of protein in a solid (bar) and liquid (drink) form on post-prandial amino acid responses in vivo in healthy young women.

Study design

Randomized, cross-over study design.

Intervention

All subjects will perform two experiments in randomized order during which they will ingest 20 g of milk protein as a drink or a bar. After ingestion, blood samples will be taken at regular intervals during a 4 hour period.

Study burden and risks

The burden and risks with participation are small. During the screening, a DEXA scan will be done to assess body composition, where the level of radiation is very low compared to the background radiation level in the Netherlands. Furthermore, we will ask the participants to fill out a medical questionnaire. Insertion of the catheter during the test days is comparable to a blood draw and could result in a small hematoma. We will take 11 blood samples during the experimental period. The total amount of blood we draw (110 mL) is much less than the amount of a blood donation (500 mL) and will be completely restored in approximately 1 month. Participants will come to the university three times: 1 screening (~1h) and 2 experimental days (~4.5h). On the experimental test day, the subjects will be asked to remain fasted (with the exception of the experimental drink or bar). In addition, subjects will be asked in the two days prior to the test day not to perform any type of intense physical activity and to avoid consuming caffeine and alcohol in the 12h and 24h prior to the test day, respectively. Participants will be asked to record their nutritional intake and daily activities in the two days prior to the experimental test day. There is no direct benefit to the participant, only their contribution to the scientific knowledge on the impact of the dietary protein matrix on post-prandial plasma amino acid responses.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Females
- Aged between 18-35 years
- Healthy, recreationally active (exercise at least 1 per two weeks and maximum 4 days a week)
- 18.5 <= BMI <= 30 kg/m2
- No physical limitations (i.e. able to perform all activities associated with daily living in an independent manner).

Exclusion criteria

- Smoking
- Lactose intolerant or allergies to milk proteins
- Musculoskeletal disorders
- Metabolic disorders
- Use of any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescribed acne medications).
- Chronic use of gastric acid suppressing medication or anti-coagulants
- Unstable weight over the last three months
- Diagnosed GI tract disorders or diseases
- Blood donation in the past 2 months
- Pregnant
- Third generation oral contraceptives

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2021
Enrollment:	14
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24741
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL77723.068.21
OMON	NL-OMON24741

Study results

Date completed: 23-03-2022

Actual enrolment: 12