The impact of milk protein glycation on protein digestion and absorption in healthy young men

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To compare the appearance of dietary protein-derived amino acids in plasma after ingestion of a milk protein powder with different levels of protein glycation in healthy young men.

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

Summary

ID

NL-OMON52897

Source
ToetsingOnline

Brief title
VerLys study

Condition

- Other condition

Synonym
Digestion & absorption, Protein breakdown & availability

Health condition

Digestie en absorptie

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: FrieslandCampina,TKI en FrieslandCampina

Intervention

Keyword: Absorption, Digestion, Glycation, Milk protein

Outcome measures

Primary outcome

The primary endpoint will be the appearance of milk protein-derived amino acids in plasma over the full assessment period (6 h), as determined using stable isotope tracer methodology.

Secondary outcome

To compare the impact of low versus high protein glycation on whole-body protein kinetics (total rate of appearance, exogenous rate of appearance, endogenous rate of appearance, rate of disappearance), whole-body protein metabolism (synthesis, breakdown, oxidation, net balance), peak plasma lysine concentration, overall plasma amino acid responses, plasma insulin-, and glucose responses.

Study description

Background summary

Protein intake is an essential stimulus for muscle protein anabolism. The muscle protein synthetic response to protein ingestion is mainly determined by the post-prandial plasma amino acid response. Milk protein often undergoes glycation during commonly applied milk processing procedures (Maillard reaction). We have previously shown that glycated protein results in lower postprandial amino acid levels. The level of protein glycation in processed dairy products might therefore be an important modulator of the overall protein

quality of a product, and its ability to stimulate protein metabolism. However, it has not yet been investigated if the glycation level of dietary protein modulates its appearance in plasma as amino acids.

Study objective

To compare the appearance of dietary protein-derived amino acids in plasma after ingestion of a milk protein powder with different levels of protein glycation in healthy young men.

Study design

Double blinded, randomized cross-over study.

Intervention

All subjects will perform two experiments in a double-blinded, randomized order: ingest 40 g of milk protein with 5% glycation level in 600 mL water, or 40 g of milk protein with 50% glycation level in 600 mL water. After ingestion, blood samples will be taken at regular intervals during a 6 hour period.

Study burden and risks

The burden and risks with participation are small. 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 catheters during the test day is comparable to a blood draw and could result in a small hematoma. We will take 15 blood samples during the experimental period. The total amount of blood we draw (150 mL each test day) 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 (~8.5h each). On the experimental test days, the subjects will be asked to remain fasted (with the exception of the experimental drinks). In addition, subjects will be asked in the two days prior to the test days 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 days, respectively. Participants will be asked to record their nutritional intake and daily activities in the two days prior to the experimental test days. There is no direct benefit to the participant, only their contribution to the scientific knowledge on the impact of protein glycation on protein digestion and absorption. The milk protein supplements are produced according to food safety standards and are safe for human use.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Males
- Aged between 18-35 years
- Healthy, recreationally active (participating in recreational sports activities >= 1 and <= 6 h per week, with a maximum of 2 h resistance-type exercise)
- 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

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):	15-03-2023
Enrollment:	17
Type:	Actual

Ethics review

Approved WMO

Date:	19-04-2022
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

No registrations found.

In other registers

Register	ID
CCMO	NL73994.068.22
Other	Registratie na goedkeuring METC