Protein requirements in healthy adult men as assessed by the Indicator Amino Acid Oxidation (IAAO) technique: a replication study

Published: 12-08-2021
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Replication study to assess dietary protein requirements in young, healthy men.

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

Summary

ID

NL-OMON50939

Source
ToetsingOnline

Brief title
IAAO study

Condition

- Other condition

Synonym
Protein requirement

Health condition

Eiwitbehoefte

Research involving
Human

Sponsors and support

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

Intervention

Keyword: indicator amino acid oxidation technique, protein requirement

Outcome measures

Primary outcome

The primary endpoint is the estimated average requirement (EAR) and recommended daily allowance (RDA) for dietary protein, which will be determined using the IAAO method by measuring 13C enrichment in expired breath and enrichment of L-[1-13C]-phenylalanine in plasma and urine.

Secondary outcome

To determine carbon dioxide production, 13CO2 production, plasma and urine L-[1-13C]-phenylalanine enrichments, and plasma and urine phenylalanine concentration in a young, healthy, male population when applying the IAAO technique.

Study description

Background summary

Dietary protein is essential for stimulating tissue renewal and growth. Current dietary protein guidelines are based on nitrogen balance studies, but the complexity of this method limits its widespread application to assess dietary requirements. The minimally invasive Indicator Amino Acid Oxidation (IAAO) technique was recently introduced as a valid way to assess dietary protein requirements. The first human study that has applied the IAAO technique to assess protein requirements was performed in 8 healthy adult men in 2008. Protein requirements defined by the IAAO technique were comparable to those defined by the nitrogen balance method. To date, this is still the only data

available on protein requirements in healthy adult men as assessed by the IAAO technique. Therefore, purpose of this study is to perform a replication study to assess protein requirements in healthy adult men as assessed by the IAAO technique in a larger sample.

Study objective

Replication study to assess dietary protein requirements in young, healthy men.

Study design

Randomized, double-blinded crossover study design.

Intervention

All subjects will consume a test diet containing 0.1, 0.3, 0.6, 0.9, 1.2, 1.5, and 1.8 g protein/kg/d during acute metabolic trials.

Study burden and risks

The burden and risks with participation are small. The risk of catheters is minimal and includes only a small hematoma. Sampling of breath and urine does not bring additional risks. All subjects will be contacted within 1 week after completing the experimental trials to ask whether they experienced any discomfort from the interventional compounds. Participants will come to the university up to eight times: 1 screening (~2 h) and 7 experimental days (~8.5 h each). Subjects will be instructed in the two days prior to the test day not to perform any type of intense physical activity and to consume a maintenance diet that will be provided by the researchers. Participants will be asked to record their daily activities in the two days prior to the first experimental test day. There is no direct benefit to the participant, only their contribution to the scientific knowledge about protein requirements and their individual protein requirement.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Male
- 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
- 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):	29-09-2021
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	12-08-2021
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: 26694
Source: NTR

Title:

In other registers

Register	ID
CCMO	NL77716.068.21
OMON	NL-OMON26694

Study results

Date completed: 25-08-2022

Actual enrolment: 12

Summary results
Trial is onging in other countries