

Re-evaluation of the muscle-full effect during continuously elevated amino acid availability in healthy young males

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To assess muscle protein synthesis rates to continuous, elevated plasma amino acid availability in healthy young males

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Muscle disorders
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON57267

Source

ToetsingOnline

Brief title

Muscle-full study

Condition

- Muscle disorders

Synonym

muscle anabolism Muscle growth

Research involving

Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Eerste geldstroom (geld van Ministerie van OC&W aan universiteiten)

Intervention

- Food (substances)

Keyword: Amino acids, Muscle, Protein synthesis

Explanation

N.a.

Outcome measures

Primary outcome

<p>Post-prandial muscle protein synthesis rates (0-8 h)</p>

Secondary outcome

<p>Muscle protein synthesis (0-2h interval, 2-4h interval, 4-6h interval, 6-8h interval) Plasma glucose, plasma insulin, plasma amino acids, plasma amino acid concentrations, 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) Relevant muscle protein signalling</p>

Study description

Background summary

Muscle tissue consists of proteins. These proteins are built up of a collection of smaller building blocks: amino acids. When protein is consumed, it gets digested and absorbed into the blood. The body can use these amino acids, by taking them up from the circulation. By consuming sufficient protein through our diet, we ensure that the body is provided with enough amino acids to enable muscle protein building. Sufficient muscle protein synthesis is important for maintaining muscle function and strength.

Previous research has shown that when 20 to 25g of protein is eaten, muscle protein synthesis is maximized. It is therefore recommended to eat 20g of protein per meal. However, it is currently unclear what happens to muscle protein synthesis rates if multiple meals are eaten. When multiple meals are consumed, amino acids appear in the circulation for prolonged period of time. Theoretically, when there are a high amino acid concentrations in the blood, muscle protein synthesis rates will increase.

Contrary to this theory, a study more than 20 years ago showed otherwise. It was observed that muscle protein synthesis rates are only elevated for 2 hours

after which they decrease again. This phenomenon was referred to as the "muscle-full" effect. Because this phenomenon is in contrast with more previous studies, the objective is to replicate that study. This is important so we can improve nutritional advice for healthy, but also clinical populations in the future.

Study objective

To assess muscle protein synthesis rates to continuous, elevated plasma amino acid availability in healthy young males

Study design

Non-randomized, non-blinded, clinical trial

Intervention

Infusion of amino acids

Study burden and risks

The burden and risks associated with this study are moderate. It is a short study (1.5 days) with a few invasive, but low-risk measurements. It is possible that for a few days there is a feeling of soreness after the biopsies which is comparable to the soreness after bumping into a table. Also, there is a possibility of some additional bleeding after the biopsies. For six biopsies this risk is present six times in total, but it is no major health risk.

Placing the cannulas during the test day can be uncomfortable and can result in a small hematoma. However, this makes the 15 blood draws relatively easy. The amount of blood that is drawn (160 mL) is way less than an average blood donation and will recover within a month. In total, participants visit the university twice, being fasted on both occasions. On the test day participants will stay fasted for a longer time, which can cause a feeling of hunger. Water drinking is allowed and unlimited. Furthermore, the participants will fill out diaries 2 days prior to the test day that will cost 30 minutes. During these days, they are also not allowed to drink alcohol or do heavy physical activities. The dexa scan provides valuable data about the body composition, but has a small radiation burden. This burden is negligible when compared to the yearly background radiation. There is no direct benefit for the participants, only their contribution to scientific knowledge. The participants will get more insight into their body composition.

Contacts

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Trial sites

Trial sites in the Netherlands

Universiteit Maastricht
Target size: 12

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Inclusion criteria

- Male sex
- Age between 18 and 35 y inclusive
- BMI between 18.5 and 30 kg/m²
- Having given informed consent

Exclusion criteria

- Smoking
- Involved in progressive exercise

- History of neuromuscular problems
- Use of anticoagulants
- Recent participation in amino acid tracer infusion studies
- Use of medication that affects (muscle) protein metabolism (e.g.corticosteroids, NSAIDs, acne medication)
- Phenylketonuria
- Diagnosed with/history of liver damage
- Diagnosed with/history of severe kidney damage and/or malfunction
- Diagnosed with the inability to break down amino acids

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Efficacy/Effectiveness

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-05-2025
Enrollment:	12
Duration:	1 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.
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IPD sharing statement

Plan to share IPD: Yes

Plan description

N.a.

Ethics review

Approved WMO

Date: 21-01-2025

Application type: First submission

Review commission: METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Notification accepted

Date: 09-05-2025

Application type: Amendment

Review commission: METC AZM/UM

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
ClinicalTrials.gov	NCT06721026
CCMO	NL87178.068.24
Research portal	NL-005463