

# The impact of ingesting a whole-food animal-based versus plant-based protein rich meal on the muscle protein synthetic response in healthy older men and women

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To compare the post-prandial muscle protein synthetic response following ingestion of a whole-food meal containing meat versus the ingestion of a meal containing only plant-based protein sources in vivo in healthy, older men and women.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON51257

### Source

ToetsingOnline

### Brief title

MeaL

### Condition

- Other condition

### Synonym

Muscle Growth, Muscle protein synthesis

### Health condition

This study will evaluate the skeletal muscle anabolic response following the ingestion of a protein rich meal

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Universiteit Maastricht

**Source(s) of monetary or material Support:** Ministerie van OC&W, National Cattlemen's Beef Association, Vion Food Group, Vion Food Group; National Cattlemen's Beef Association

## Intervention

**Keyword:** Muscle protein synthesis, Omnivorous, Vegan

## Outcome measures

### Primary outcome

The primary endpoint will be mixed muscle protein synthesis rates over the full 6h post-prandial period following meal ingestion.

### Secondary outcome

Plasma glucose, insulin and amino acid concentrations, as well as breath  $^{13}\text{C}/^{12}\text{C}$  ratio following meal ingestion.

## Study description

### Background summary

Food intake stimulates muscle protein synthesis rates. The magnitude of the anabolic response to feeding forms a key factor in regulating muscle mass maintenance. Ingestion of animal-derived proteins generally leads to a greater stimulation of muscle protein synthesis when compared to the ingestion of plant-derived proteins. What is often neglected is that the anabolic properties of protein isolates do not necessarily reflect the anabolic response to the ingestion of the whole-foods from which they are derived. This discrepancy is due to the presence or absence of other components normally found within whole-food matrices, which influence protein digestion and amino acid absorption from animal based and plant based protein sources. A rapid and robust post-prandial release of food-derived amino acids is of particular relevance for older individuals, who typically show a blunted muscle protein

synthetic response to feeding

## **Study objective**

To compare the post-prandial muscle protein synthetic response following ingestion of a whole-food meal containing meat versus the ingestion of a meal containing only plant-based protein sources in vivo in healthy, older men and women.

## **Study design**

randomized, counter-balanced, cross-over design, researchers and participants are not blinded, analysts are blinded.

## **Intervention**

Participants will undergo 2 test days. On one test day participants will consume a meal containing meat, the other day participants will consume a meal without meat.

## **Study burden and risks**

The burden and risks involved in participating in this experiment are small. Participants will visit the University on three occasions (screening + 2 test days). The first visit will involve a screening visit (~2 h), during which the eligibility of the participant will be assessed. During the screening visit, a medical questionnaire is filled out, and a DEXA scan will be performed to assess body composition, where the level of radiation is very low compared to the background radiation level in the Netherlands.

The participants will participate in 2 test days of ~12h. Insertion of the catheters during the test days is comparable to a normal blood draw and the only risk is a small local hematoma. During each of the 2 experimental test days 16 blood samples (170mL/day) will be obtained. The total amount of blood collected during this study is less than the amount of a blood donation and will be completely restored in approximately 1 month. The stable isotope amino acids tracers that will be infused intravenously during the experimental trial are produced according to GMP standards and are safe for human use. Throughout each test day, muscle biopsies will be obtained under local anaesthesia by an experienced physician, but may cause some minor discomfort. The discomfort is comparable to muscle soreness or the pain one has after bumping into the corner of a table. Additional expired breath samples will be collected and analysed for  $^{13}\text{C}/^{12}\text{C}$  ratio, this procedure is comparable to gently exhaling in a balloon and does not involve any risks.

For each visit participants are required to come to the university in a fasted state, not having consumed any food or beverages (except for water) as from 22:00 the evening before. Also, 2 days prior to the experimental test days

participants need to record their food intake and activities performed. During these 2 days participants are not allowed to perform heavy physical exercise or drink alcohol. There is no direct benefit for the participants, except from their contribution to scientific knowledge on the impact of whole food protein ingestion on stimulation of muscle protein synthesis.

## Contacts

### Public

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### Scientific

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Aged 65-85 years
- Body mass index  $18.5 \times 30 \text{ kg/m}^2$
- Healthy
- Having given informed consent

## Exclusion criteria

- Allergy for one of the food items used
- >5% weight change in the previous 6 months
- Blood pressure >140/90 mmHg
- Participating in a structured (progressive) exercise program
- Smoking
- Diagnosed musculoskeletal disorders
- Diagnosed metabolic disorders (e.g. diabetes)
- Use of any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories).
- Chronic use of gastric acid suppressing medication
- Chronic use of anti-coagulants
- Recent (<1 year) participation in amino acid tracer (L-[ring-<sup>13</sup>C<sub>6</sub>]-phenylalanine and L-[3,5-<sup>2</sup>H<sub>2</sub>]-tyrosine studies
- Diagnosed GI tract disorders or diseases
- Blood donation in the past 2 months
- Strict vegan diet

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	28-06-2021
Enrollment:	31
Type:	Actual

## Ethics review

Approved WMO

Date: 04-05-2021

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

No registrations found.

### In other registers

#### Register ID

CCMO NL76626.068.21

Other Protocol will be registered at ClinicalTrials.gov after approval by the METC