The effect of ingesting a novel fortified plant-based protein mix on acute muscle protein synthesis in older people.

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To assess postprandial muscle protein synthesis rates in older males in response to ingesting a blend of plant protein fortified with free leucine as compared to (gold standard) whey protein and compared to a plant protein blend without additional...

Ethical review	Approved WMO
Status	Completed
Health condition type	Muscle disorders
Study type	Interventional

Summary

ID

NL-OMON53419

Source
ToetsingOnline

Brief title
Strongplant Study

Condition

- Muscle disorders

Synonym
muscle anabolism, Muscle growth

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Danone Vitapole,Danone;TKI Agri-Food

Intervention

Keyword: Muscle, Older, Plant, Protein

Outcome measures

Primary outcome

4-hour postprandial muscle protein synthesis rates in rest

Secondary outcome

Plasma amino acid concentrations

Plasma glucose/insulin concentrations

Relevant signalling pathways

Gastrointestinal-palatability scores

Study description

Background summary

Muscles are built up out of proteins. These proteins consist of little buidling blocks: Amino acids. Bij consuming sufficient protein in our nutrition, makes sure our body has enough building blocks to maintain or increase our muscle mass. Taking into consideration that de world population is growing, it will be challenging to have suffient supply of animal-derived protein sources. Plant-derived proteins can be produced on a more sustainable scale and can therefore contribute to feeding the future world population. Because the protein quality of plant-derived proteins is not optimal, these are commonly consumed as mixtures. Adding isolated amino acids is a strategy to further improve the protein quality.

Study objective

To assess postprandial muscle protein synthesis rates in older males in response to ingesting a blend of plant protein fortified with free leucine as compared to (gold standard) whey protein and compared to a plant protein blend without additional free leucine.

Study design

randomized, parallel-group, double-blind intervention trial.

Intervention

20g protein as whey, plant-blend, or fortified plant-blend

Study burden and risks

The burden and risks associated with participation in this study are low.
Placing the cannulas is comaprable to a bloodprick and can in some cases lead to a small hematoma. The muscle biopsies are taken by an experienced physician under local anaesthesia, but in some cases can be painful upto 24h after the biopsy. This pain is comparable to the soreness after bumping into a table. Also, there is a risk of some additional bleeding, but this is no major health risk. We will take in total 18 blood samples (190 mL), which is less than half of a blood donation and this will normally recover within a month.
Participants will visit the university twice: 1 screening (2h) and 1 test day (9h), being fasted (no food and drinks, only water) on both occasions from 22:00 pm the evening before. Besides, they will maintain their habitual dietary- and activity pattern 3days prior to the test day, but refraining from heavy physical activity and alcohol consumption. They will also record their acivity pattern and food intake during the 2 days prior to the test day. On the screening they will fill in a medical questionnaire.
The dexa scna provides valuable data about the body composition, but has a small radiation burden. This burden is neglegible when compared to the yearly background radiation.
During the test day blood and muscle samples will be taken and participants will consume a drink.
There is no direct benefit for the participants, only their contribution to scientific knowledge, which can be applied in the future. The participants will get more insight into their body composition.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

Universiteitssingel 50
Maastricht 6229ER
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

Universiteitssingel 50

Maastricht 6229ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Male sex
Aged between 60 and 85 y inclusive
BMI between 18.5 and 35 kg/m2

Exclusion criteria

Vegan/vegetarian diet
Intolerant to milk products
Soy allergy
Pea allergy
Participating in a structured (progressive) exercise program
Smoking regularly (i.e. >5 cigarettes/week)
Diagnosed GI tract disorders or diseases
Diagnosed musculoskeletal disorders
Diagnosed metabolic disorders (e.g. diabetes)
Diagnosed with phenylketonuria (PKU)
Uncontrolled hypertension (blood pressure above 160/100 mmHg)
Donated blood 3 months prior to test day
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 studies

(L-[ring-13C6]-phenylalanine and L-[3,5-2H2]-tyrosine)

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	21-09-2023
Enrollment:	45
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2022
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	09-08-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-03-2024
Application type:	Amendment
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	NL82127.068.22