The effectiveness of daily protein supplementation with a plant protein blend vs milk protein to support integrated muscle protein synthesis rates with and without exercise in healthy older individuals.

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To assess the effectiveness of daily protein supplementation with either a plant based protein blend or a milk protein on top of a standard diet to stimulate integrated muscle protein synthesis rates in healthy older individuals with and without...

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

Summary

ID

NL-OMON57104

Source ToetsingOnline

Brief title Blend-D2O

Condition

Muscle disorders

Synonym

Muscle anabolism, Muscle growth

Research involving

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Human

Sponsors and support

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

Intervention

Keyword: Exercise, Muscle, Older, Protein

Outcome measures

Primary outcome

10-day muscle protein synthesis rates %/day in the non-exercised leg.

Secondary outcome

10-day muscle protein synthesis rates %/day in the exercised leg.

Muscle crosssectional area measured with ultrasound.

Study description

Background summary

Nutrition contains protein. The protein is made up of building blocks, called amino acids. Following ingestion, these will be taken up by the gut and appear in the blood. Blood transports the amino acids to the muscles and other organs. Consumption of sufficient protein facilitates the availability of sufficient amino acids for muscle protein accretion. Muscle protein accretion is required to maintain and improve muscle health and enables us to walk, cycle, but also exercise.

Nutrition guidelines prescribe a protein threshold of at least 0.8g protein/ kg body mass/day, but is it suggested that older individuals should ingest more protein. It is difficult to ingest sufficient protein through food products only and thus ingestion of protein powders would be a strategy to improve protein intake. Plant protein can be produced in a more sustainable way, but the amino acid composition is suboptimal. Blending different plant proteins would be a good way to improve the amino acid composition and thereby protein quality similar to milk protein. This way both a plant protein mix and milk protein could contribute to muscle accretion by increasing protein intake.

Study objective

To assess the effectiveness of daily protein supplementation with either a plant based protein blend or a milk protein on top of a standard diet to stimulate integrated muscle protein synthesis rates in healthy older individuals with and without exercise.

Study design

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

Intervention

consumption of twice daily placebo (carbohydrates), plant blend (2x 20g protein pea-corn-blend) or milk protein (2x 20g protein from milk protein concentrate) while adhering to a diet containing 0.8g protein/kg body mass/d.

Study burden and risks

The burden and risks associated with participation in this study are moderate. The participants will visit the university 4x after an overnight fast for measurements (3 hours max). They will fill out a single medical questionnaire. They will adhere to a prescribed nutrition pattern for 14 days. They will daily ingest heavy water, sample saliva, and consume twice daily supplements. They will also wear a step counter.

The venapunction can be unpleasant and result in a small hematoma. Biopsies will be obtained by an experienced physician. participants can experience stiffness in the thigh muscle for a few days after the biopsy and these days there is a small risk for additional bleeding. Because of the 3 biopsies this risk is present 3 times, but should not pose a big health concern. The ingestion of heavy water has been applied in

numerous published studies and is entirely safe and non-toxic in the amounts provided in the present study. Diets and supplements will be composed of commercially available products.

The dexa scan provides insight in the body composition, but involves a small dose of radiation, which is negligible and comparable to the yearly background radiation dose.

There is no direct benefit for the participants when participating. They will get insight into their body composition (DEXA) and receive 14 days worth of food, which will decrease living expenses for that period.

Contacts

Public

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Universiteit Maastricht

Universiteitssingel 50 Maastricht 6229ER NL **Scientific** Universiteit 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 or Female sex Aged between 60 and 80 year inclusive BMI between 18.5 and 30 kg/m2

Exclusion criteria

- Following a self-reported vegetarian and vegan diet the 6 months prior to the study.

- Intolerant to milk products
- Corn allergy
- Pea allergy
- Participating currently or in the 3 months prior to the study in a structured (progressive) exercise program.
- Smoking regularly (i.e. >5 cigarettes/week)
- Disease history or use of medication that affects participation in study or

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outcomes (assessed by MD)

- Uncontrolled hypertension (blood pressure > 160/100 mmHg)
- pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

No

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	26-06-2024
Enrollment:	42
Туре:	Actual

Medical products/devices used

Registration:	
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Ethics review

Approved WMO	
Date:	18-04-2024
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 CCMO ID NL85365.068.23