The effect of plant and animal protein supplements on muscle damage: An explorative study

Published: 29-06-2021
Last updated: 15-05-2024

To investigate the impact of different types of proteins on muscle damage upon an endurance exercise bout in elderly.

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

Summary

ID

NL-OMON51231

Source
ToetsingOnline

Brief title
Protein supplements and muscle damage

Condition

- Muscle disorders

Synonym
decrease in musscle mass, Sarcopenia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: NewCare

Intervention

Keyword: Muscle damage, Physical exercise bout, Protein supplementation

Outcome measures

Primary outcome

The primary outcome is CK-level in blood after a prolonged exercise bout.

Secondary outcome

Secondary study parameter are muscle strength, muscle mass and muscle pain.

Study description

Background summary

Rationale: Loss of skeletal muscle mass and strength is a consequence of aging. Especially essential amino acids are key nutrients for muscle health in elderly adults. A protein intake of 1.2-1.5 g/kg/day is recommended for elderly, but more than half of the elderly do not reach this daily protein intake recommendation. Until today, humans consume more proteins from animal sources compared to plant-based sources. Though, the consumption of animal-based proteins in the aging population brings disadvantages such as an increased risk for cardiovascular disease and various cancers. Because of that, it seems more advisable to increase protein intake of elderly with plant-based proteins. In this study, we want to investigate the effect of various types of a plant-based protein on aging muscles.

Study objective

To investigate the impact of different types of proteins on muscle damage upon an endurance exercise bout in elderly.

Study design

This explorative study is a double-blind randomized controlled trial. For 2 subsequent weeks, the effects of a daily 1) plant-based protein, 2) whey protein, or 3) a placebo supplementation, on muscle damage, muscle mass and muscle strength will be investigated.

Intervention

The subjects will be randomly assigned to a protein or placebo supplement group. It will be consumed as a drink or smoothie. Upon completion of the 2-week supplement consumption, subjects will be asked to perform once an endurance exercise bout of walking 30 kilometres.

Study burden and risks

The risks involved in participating in this experiment are minimal. The protein supplements provided are generally available existing products with no adverse effects. Protein and placebo supplements will be produced under Good Manufacturing Practices in certified facilities and using approved and commercially available ingredients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Aged 60 and higher
- Able to walk 20-30km in 1 day
- able to understand and follow the study procedures

Exclusion criteria

- Diabetes
- Lactose intolerance or milk allergy
- BMI >30kg/m2
- Diagnosed with COPD
- Diagnosed with kidney failure
- Diagnosed with a bowel disease that influences protein uptake, such as inflammatory bowel disease or Crohn's disease.
- Consumption of other freely available protein supplements on their own during the inclusion period and the study period of about 1 month.
- If the subject intends to perform additional prolonged exercise bouts in the 4 days before and the 4 days after the studied exercise bout of walking 20-30 kilometres.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-07-2021
Enrollment:	60

Type:	Actual

Ethics review

Approved WMO Date:	29-06-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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: 24234
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77522.091.21
OMON	NL-OMON24234

Study results

Date completed:	24-09-2021
Actual enrolment:	47

Summary results
Trial is onging in other countries