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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24234

Source
Nationaal Trial Register

Brief title
Protein supplements and muscle damage

Health condition

Sarcopenia

Sponsors and support

Primary sponsor: New Care
Source(s) of monetary or material Support: New Care

Intervention

Outcome measures

Primary outcome

muscle damage (serum creatine kinase (CK) and lactate dehydrogenase (LDH)

Secondary outcome

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 active 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.
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 placebo-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.
Study population:
The study population includes 20 participants in each of the three study groups of people aged 60 years and above, who are capable of performing an endurance exercise bout.
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.
Main study parameters/endpoints:
The primary outcome is CK-level in blood after a prolonged exercise bout. Secondary study parameters are muscle strength, muscle mass and muscle pain.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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.

Study objective

Protein supplementation will result in less muscle damage

Study design

The primary outcome, muscle damage, is measured in venous blood by the assessment of the level of serum creatine kinase (CK) and lactate dehydrogenase (LDH).
Blood is collected in 5 occasions: 1) 1 week before the two-week protein consumption, 2) the day after the last protein consumption and before the physical endurance bout, 3) the day after the physical endurance bout, 4) and 5) on the second and third day after the physical endurance bout
The secondary outcomes muscle strength, muscle mass and muscle pain are measured on the same timepoints as described for the primary outcome. The used methods are;
Muscle strength: Maximal handgrip strength is measured to the nearest 0.5 kg using a hand dynamometer. The subject is seated in a chair with the shoulders adducted and neutrally rotated and elbow flexed at 90°. Three consecutive measures of handgrip strength (kg) will be recorded.
Maximal voluntary contraction of the quadriceps muscle will be measured by asking subjects to produce three maximal voluntary knee extensions of approximately three seconds, with a one-minute rest period in between while being seated on a specially designed chair with the pelvis and upper thigh securely fixed to the seat and the knee angle at 100◦ extension.
Muscle mass: calculated by bioimpedance analyses, as well as BMI, hip and waist circumference
Muscle pain: A short questionnaire about muscle complaints is filled in during all 5 visits. It is an adjusted Cornell Musculoskeletal Discomfort Questionnaire which will help us getting insight in muscle pain/complaints of the subjects.

Intervention

Protein supplementation and physical endurance bout

Contacts

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Eligibility criteria

Inclusion criteria

- 60 years of older
- Participation in the 4 Day Marches Nijmegen in earlier years
- Capable of walking 30 kilometres on one day
- Able to understand and perform the study procedures

Exclusion criteria

- Type I or Type II diabetes
- Allergic or sensitive for milk proteins, or lactose intolerant
- BMI >30kg/m2
- Diagnosed COPD
- Diagnosed renal insufficiency
- Diagnosed intestinal diseases influencing the uptake of protein (i.e. active inflammatory bowel disease, 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 30 kilometres.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2021

Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Plan description
upon reasonable request we can share the data

Ethics review

Positive opinion

Date:	28-05-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51231
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9499
CCMO	NL77522.091.21
OMON	NL-OMON51231

Study results