The effect of mealworm protein on muscle damage in active vital elderly

Published: 22-03-2022
Last updated: 29-08-2024

To investigate the impact of the daily consumption of a mealworm- and whey protein supplement on muscle damage upon physical exercise in vital active elderly.

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

Summary

ID

NL-OMON50607

Source
ToetsingOnline

Brief title
Mealworm protein and muscle damage

Condition

- Muscle disorders

Synonym
decrease in musscle mass and function, Sarcopenia

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Protifarm BV, Ynsect Human Nutrition and Health,Protifarm BV;Ynsect Human Nutrition and Health

Intervention

Keyword: Mealworm protein, Muscle damage, Physical exercise

Outcome measures

Primary outcome

The primary outcome is the muscle damage biomarkers Creatine Kinase in blood.

Secondary outcome

Body composition, muscle strength, blood lipids and inflammatory markers will be measured as secondary study parameters. Via questionnaires the intake compliance, consumer satisfaction, muscle soreness, general physical activity- and food consumption patterns will be assessed.

Study description

Background summary

Elderly are confronted with a gradual loss of skeletal muscle mass, strength and function as a consequence of aging (sarcopenia). Moreover, older adults exhibit higher levels of muscle damage upon a physical exercise bout compared to younger adults. Physical activities result in micro injuries to contractile proteins, so-called muscle damage, as demonstrated by elevated muscle soreness and an increase in plasma creatine kinase (CK). The intake of dietary proteins may augment muscle repair through accelerating muscle protein turnover, which is of great relevance elderly. Protein from insects has the potential of being an eco-friendly and high-quality solution to meet future protein demands. Previous studies in humans have shown that insect protein is equivalent in terms of nutritional value compared to milk-derived protein. Moreover, the ingestion of mealworm protein resulted in a substantial increase in postprandial blood amino acid levels. Muscle protein synthesis rates, both at rest and during recovery from exercise, were comparable upon the consumption of a mealworm- or milk-derived protein supplement. Until now, human studies using mealworm have been conducted in small groups of young participants and only the effects upon acute exposure has been studied. Therefore, the current study was designed to assess the effects of mealworm supplementation for three consecutive months in older vital individuals.

Study objective

To investigate the impact of the daily consumption of a mealworm- and whey protein supplement on muscle damage upon physical exercise in vital active elderly.

Study design

Double-blind randomized placebo-controlled trial. The effects of daily supplementation for 3 subsequent months, of 1) mealworm, 2) milk-derived protein, or 3) an iso-caloric placebo, on muscle damage upon physical exercise will be measured. Muscle damage will be induced by repeated bouts of prolonged walking exercise (30-50 km per day) on 4 consecutive days. Since this study will be the first to provide long-term mealworm protein supplementation, we will also repeatedly measure body composition, muscle strength, blood lipids and inflammatory markers to obtain valuable insights into other health effects of mealworm protein.

Intervention

Subjects will be randomly assigned to one of the three groups. Daily supplementation will be consumed at two doses/day (15 gram/dose), during breakfast and after an exercise bout (or on days without exercise, during lunch). Upon 3 months of supplement consumption, subjects will participate in the Nijmegen Four Days Marches and they will walk 30-50 km on a self-selected pace for four consecutive days. During the Nijmegen Four Days Marches the protein/placebo supplement will also be consumed. Before, during and after the protein supplementation and during the Nijmegen Four Days Marches event, repeated blood sampling will be performed as well as the measurement of body composition, muscle strength and the request to complete online questionnaires.

Study burden and risks

The risks involved in participating in this research are negligible. The protein supplements provided are commercially available products with no reported adverse effects. Protein and placebo supplements will be produced according to the HACCP/ISO22000 regulations in certified facilities and using approved ingredients. Most study procedures do not involve any risks for the subjects. Measurements with a limited burden are blood sampling which is associated with a 5% risk of developing a haemorrhage, but will fully disappear within 2 weeks and is not associated with any (functional) limitations. Based on previous studies, the two protein supplemented groups might benefit from improved physical performance and reduced muscle soreness during and after the Nijmegen Four Days Marches. All subjects will receive a summary of the obtained study results after completion of the study.

Contacts

Public
Radboud Universitair Medisch Centrum

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL
Scientific
Radboud Universitair Medisch Centrum

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 60 years of older
- Registered for the Nijmegen Four Days Marches 2022
- 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
- Allergic or sensitive for shell and shellfish, like shrimp
- BMI >30kg/m2
- Diagnosed COPD

- Currently treated for cancer
- 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 total study period of about 4 months
- Use of statins
- Involved in a heavy resistance type exercise program

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):	11-04-2022
Enrollment:	70
Type:	Actual

Ethics review

Approved WMO

Date:	22-03-2022
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: 21181
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL79716.091.21
NTR-new	NL9862

Study results

Date completed:	22-07-2022
Actual enrolment:	70