A pilot study in the effect of mealworm protein on muscle damage in active vital elderly

Published: 08-11-2021
Last updated: 31-08-2024

We hypothesize that the ingestion of both lesser mealworm and whey protein (30 g per day for three subsequent months) will lead to less muscle damage upon the repeated physical exercise compared to the iso-caloric placebo.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21181

Source
Nationaal Trial Register

Brief title
Mealworm protein and muscle damage

Health condition

Sarcopenia

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Protifarm

Intervention

Outcome measures

Primary outcome

To investigate the impact of additional protein intake of the lesser mealworm on muscle damage (serum creatine kinase (CK) and lactate dehydrogenase (LDH)) due to repeated physical exercise (walking 30-50 km) in vital active elderly.

Secondary outcome

The secondary study parameters are body composition, muscle strength, blood lipids and inflammatory markers.

Study description

Background summary

Rationale: Elderly are confronted with a gradual loss of skeletal muscle mass, strength and function as a consequence of aging. Enhanced protein intake is therefore recommended to elderly. Protein from insects has the potential of being an eco-friendly, high-quality solution to meet future protein demands. Previous studies in human subjects have shown that insect proteins are 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. The 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, we designed a pilot study for the assessment of the longer term effects of mealworm ingestion in older vital individuals. Objective: The present pilot study has been designed to investigate the impact of the daily consumption of a mealworm protein supplement on muscle damage in vital active elderly. Since this study will be the first to provide the mealworm protein supplementation on a daily basis for three subsequent months, we also include several secondary study parameters to obtain also valuable insights into other health effects of mealworm protein. Study design: This study is a 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 and several secondary study parameters will be investigated. Muscle damage will be induced by repeated physical exercise (walking 30-50 km). Study population: The study population includes 69 participants divided in three study groups (n=23/group) of active healthy volunteers aged 60 years or above. The participants are recruited via the Nijmegen Exercise Study (study-id: NL36743.091.11) database. Intervention: The subjects will be randomly assigned to an intervention group. The 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 walk the Four Days Marches of 30-50 km a day. During the Four Days Marches the protein/placebo supplement will also be consumed. Before, during and after the protein supplementation and during the Four Days Marches event, repeated blood and urine sampling will be performed as well as the measurement of body composition, muscle

strength and the request to fill in online questionnaires. Main study parameters/endpoints: The primary outcome is muscle damage biomarkers (CK and LDH) in blood. Body composition, muscle strength, objective physical activity, 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. Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks involved in participating in this research are minimal. The protein supplements provided are available existing products with no adverse effects. Protein and placebo supplements will be produced according to the HACCP/ISO22000 regulations in certified facilities and using approved ingredients. Most 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 intervention group might benefit from improved physical performance and reduced muscle soreness during and after the Four Days Marches. All subjects will receive a summary of the obtained study results and their personal measurement results after completion of the study.

Study objective

We hypothesize that the ingestion of both lesser mealworm and whey protein (30 g per day for three subsequent months) will lead to less muscle damage upon the repeated physical exercise compared to the iso-caloric placebo.

Study design

With respect to the participants, the full study comprises a period of about four months. Inclusion first participant will be around April 4, 2022 The subjects will be randomly assigned to a protein or iso-caloric placebo supplement group. The daily supplementation will be consumed at two doses/day, during breakfast and after an exercise bout (or on days without exercise, during lunch). Upon three months of supplement consumption, subjects will walk the Four Days Marches of either 30, 40 or 50 km a day. During the Four Days Marches, the protein/placebo supplement will also be consumed. Before, during and after the protein supplementation and during the Four Days Marches event, repeated blood sampling will be performed as well as the measurement of body composition, muscle strength and the request to fill in online questionnaires. End of study procedures will be around July 24, 2022

Intervention

The subjects will be randomly assigned to a protein or iso-caloric placebo supplement group. The daily supplementation will be consumed at two doses/day, during breakfast and after an exercise bout (or on days without exercise, during lunch). Upon three months of supplement consumption, subjects will walk the Four Days Marches of either 30, 40 or 50 km a day.

Contacts

Public
Radboudumc
Marcia Spoelder-Merkens

0614399980
Scientific
Radboudumc
Marcia Spoelder-Merkens

0614399980

Eligibility criteria

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-04-2022
Enrollment:	69
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description
upon reasonable request we can share the data

Ethics review

Positive opinion

Date:	08-11-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50607
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9862

Register	ID
CCMO	NL79716.091.21

Study results