Evaluation of a novel alternative protein source to stimulate post-exercise muscle protein synthesis

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From p11 of C1 protocol document:1) To define the characteristics of mealworm protein ingestion on protein/digestion absorption kinetics and both whole-body and myofibrillar muscle protein synthesis after a single bout of resistance exercise in...

Ethical review	Approved WMO
Status	Completed
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON47452

Source
ToetsingOnline

Brief title
Mealworm protein

Condition

- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym
muscle growth, Muscle protein synthesis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Alternative protein source, Muscle Protein Synthesis, Resistance Exercise

Outcome measures

Primary outcome

From p23 of C1 protocol document:

The main study endpoint is the fractional synthetic rate (FSR) of muscle protein synthesis (myofibrillar proteins) from 0-5 hours in the post-prandial period.

Secondary outcome

From p23 of C1 protocol document:

* The fractional synthetic rate (FSR) of muscle protein synthesis (myofibrillar proteins) from -3-0, 0-2 and 2-5 hours in the postabsorptive and post-prandial period respectively.
* Plasma free phenylalanine enrichment (expressed as MPE)
* Plasma free tyrosine enrichment (expressed as MPE)
* Plasma total phenylalanine (expressed as *mol/L)
* Plasma total tyrosine (expressed as *mol/L)
* Total plasma amino acids (AAmax [*mol/L])
* Plasma glucose (glucosemax [mmol/L])
* Plasma insulin (insulinmax [mU/L])
* Plasma total phenylalanine, leucine and tyrosine concentrations (expressed as

*mol/L)

Study description

Background summary

From p8 of C1 protocol document:

Sufficient dietary protein ingestion on a daily basis is needed to supply the muscles with amino acids to enable the process of muscle protein synthesis. However, the production of sufficient amounts of animal-based protein from conventional sources to meet future global food demands represents a challenge. Edible insects have been proposed as an alternative source of dietary protein that can be produced on a viable and more sustainable commercial scale and, as such, may contribute to ensuring global food security. Many edible insects represent a rich source of protein, comparable to conventional meat and fish, and provide EAA in amounts comparable to certain high quality protein sources. However, there is currently limited data on the functional capacity of insect-based protein sources.

Study objective

From p11 of C1 protocol document:

1) To define the characteristics of mealworm protein ingestion on protein/digestion absorption kinetics and both whole-body and myofibrillar muscle protein synthesis after a single bout of resistance exercise in young men and 2) compare the response of mealworm vs. milk protein ingestion on protein/digestion absorption kinetics and both whole-body and myofibrillar muscle protein synthesis after a single bout of resistance exercise in young men.

Study design

From p12-13 of C1 protocol document:

2.1 Screening
When volunteers respond to the advertisement, we will contact them by e-mail/phone and briefly explain the study. We will provide them with the information brochure and the informed consent (which they will bring during the screening). To assess whether volunteers are eligible to participate in this study, we will invite them to the University for screening. Before we start the screening, we will explain the entire experimental trial and answer any potential questions. We will then ask them to read, fill out, and sign the

informed consent form. After signing the informed consent form, we will start the screening by going through the medical questionnaire to assess their general health, use of medication, and physical activity. Subsequently, we will assess body composition by performing a dual-energy X-ray absorptiometry (DEXA) scan and measure body height and body weight. DEXA is a simple and non-invasive procedure, which will take place at the University. Subjects will be instructed to lie down on a table and stay motionless for approximately 3 minutes during which the body scan takes place. Performing the above mentioned tests allow us to characterize the participants. In case of an unexpected medical finding, it is our duty to inform the subjects. If a participant does not want to receive this information, he cannot participate in this study.

Following the DEXA scan and anthropometric measurements, subjects will be familiarized and tested for strength on the exercise machines. Subjects will be instructed on proper single legged weight-lifting technique on each exercise machine (leg-press and leg-extension) and complete a standardized testing protocol to determine a measurement of maximal strength (1RM) for one leg on each exercise machine. The testing protocol requires that the subjects complete sets on each exercise machine increasing in weight until volitional fatigue occurs, ideally occurring between 3-6 repetitions on the heaviest weight. The attained strength data will be compared to previously published data and used to calculate an estimation of 1RM. Following the determination of 1RM, subjects will be scheduled for their experimental testing day.

2.2 Experimental trial

An outline of the study protocol is shown in Figure 1. At 8.00 am, following an overnight fast, subjects will arrive at the laboratory by car or public transportation. Subjects will rest in a supine position and a Teflon catheter will be inserted into an antecubital vein for intravenous stable isotope infusion. A second Teflon catheter will be inserted in a heated dorsal hand vein of the contralateral arm and placed in a hot-box (60°C) for arterialized blood sampling. Following basal blood collection (8 mL; t= -180 min), the plasma phenylalanine and tyrosine pool will be primed with a single intravenous dose of tracer and a continuous tracer infusion will commence. Arterialized blood samples (8 mL) will then be drawn at t= -180, -120, -60 and 0. Starting at -60 (min), subjects will perform unilateral resistance exercise. Immediately after the exercise subjects will return to the resting supine position and arterialized blood sample will be drawn. Afterwards, a muscle biopsy from both legs will be collected (t= 0 min). Subjects will then receive their respective nutritional treatment (t= 0). Arterialized blood samples (8 mL) will be collected at t= 20, 40, 60, 90, 120, 150, 180, 240 and 300 min during the post-exercise recovery period. At 120 min, again a muscle biopsy will be taken from both legs but from a different incision. Finally, at 300 min the last biopsies will be taken from both legs. In total, six muscle biopsies will be taken through six separate incisions during the trial. The muscle biopsies (immediately, 2 h, and 5 h after exercise) will allow us to measure the temporal response of muscle protein synthesis of mealworm and milk protein

ingested after exercise. The muscle biopsies at 0, 2 and 5 hours post-exercise will provide us with a better insight in the differences between *early* (0-2 h) and *late* (2-5 h) muscle protein synthesis response. The first blood sample at t= -180 together with the first biopsy from the rested leg at t= 0 allow us to calculate resting muscle protein synthesis rates prior to exercise and protein ingestion.

Intervention

From p17 of C1 protocol document:

Subjects will perform unilateral resistance exercise and consume either 30 g mealworm or milk protein. In addition, continuous intravenous tracer infusions will be applied, with plasma and muscle samples collected. The exercise session consists of a 5 min unilateral warm-up on a cycle ergometer and 4 unilateral sets on the leg-press and leg-extension machines. The workload is set at 80% of the subjects* one-repetition maximum (8*10 repetitions) to stimulate muscle hypertrophy. Resting periods of 2 min are allowed between sets and 2 min between exercises.

Study burden and risks

From p31-32 of C1 protocol document:

The burden and risks associated with participation are medium. Insertion of the catheters is comparable to a blood draw and could result in a small hematoma. Muscle biopsies will be taken under local anesthesia by an experienced physician, but may cause some minor discomfort for maximally up to 24 h after completion. The discomfort is comparable to muscle soreness or the pain one has after bumping into a table. We will take 13 blood samples (104 mL total) during the experimental trial respectively. The total amount of blood we draw is less than half the amount of a blood donation and will be completely restored in approximately 1 month. For the experimental trial, participants have to be fasted, so they are not allowed to eat and drink (except for water) from 22h00 the evening before. Also 3 days prior to the experimental trial participants should not perform any type of intense physical exercise, and should not consume alcohol. Thereby, participants will be asked to keep their diet as constant as possible for 3 days and to fill out a dietary and activity record for 3 days prior to the experimental trial.
The milk protein used in the beverages is similar to normal milk and also commercially available as a food product, same as the mealworm protein. Therefore, the test beverages do not form any health risks. The stable isotope amino acids tracers applied in this experiment are not radioactive and are completely safe. The production of the tracers for intravenous administration will occur in a sterile environment according to GMP guidelines.
There is no risk associated with the DEXA scan. The radiation dose emitted

during a DEXA scan is 0.001 mSv. This is a very low exposure compared to the total background radiation in the Netherlands, which is ~2.5 mSv/year. For comparison, the radiation dose during a flight higher than 10 km is 0.005 mSV*h-1. Performing exercise will pose little risk as the possibility for adverse health events will be evaluated during the screening and subjects will be closely monitored throughout the exercise session.
There is no direct benefit for the participants, only their contribution to scientific knowledge on insects as a sustainable alternative source of dietary protein for human consumption.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Healthy males

* Age between 18 and 35 y inclusive
* BMI between 18.5 and 30 kg/m2

Exclusion criteria

* Use of tobacco products
* Non-steroidal anti-inflammatory drugs (NSAID) in the 4 days prior to the experimental trial
* Allergies to milk proteins (whey or casein)
* Allergies to house dust mites or crustaceans
* Lactose intolerance
* Phenylketonuria (PKU)
* Blood donation within 2 months of study initiation
* Arthritic conditions
* A history of neuromuscular problems
* Previous participation in amino acid tracer studies
* Individuals on any medications known to affect protein metabolism (i.e. corticosteroids, non-steroidal anti-inflammatories, or prescription strength acne medications)
* Diabetes
* Training more than 5 days per week

Study design

Design

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	13-03-2018
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2016
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

ID: 24702
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL58529.068.16
OMON	NL-OMON24702