Impact of protein supplementation on running-induced muscle soreness and muscle damage

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

Summary

ID

NL-OMON46050

Source
ToetsingOnline

Brief title
Prorunning

Condition

- Muscle disorders

Synonym
muscle damage, Muscle soreness

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Endura nce athlete, Muscle damage, Muscle soreness, Protein

Outcome measures

Primary outcome

The primary outcome in this study is muscle soreness at 24 hours after the exercise event for which the visual analog scale (VAS) will be used.

Secondary outcome

Secondary outcome measures include the VAS score at 48 and 72 hours after the event, the Short-Form Brief Pain Inventory (BPI-SF) questionnaire to examine muscle soreness and muscle complaints and the Short-Form Brief Fatigue Inventory (BFI-SF) to assess the level of fatigue. Moreover, in a subsample of 50% (n=208) one venous blood sample will be collected between 24 to 48 hours post-exercise to determine the muscle damage markers CK and lactate dehydrogenase (LDH) concentrations. In the same subsample perceived muscle soreness measured will be measured with a strain gauge algometer.

Other important outcomes are habitual protein ingestion using a 24h recall, protein intake on the race day and 2 days post-exercise, medical history, rating of perceived exertion during the race, finish times, average heart rate during the run, training status and habitual physical activity and exercise training levels using the Short QUestionnaire to Assess Health-enhancing physical activity (SQUASH) and whether participants performed other exercises in the 2 days after the race.

Study description

Background summary

Most exercise recovery stra tegies for endurance type athletes solely focus on refueling and rehydration, without taking skeletal
muscle repair and recovery into account. However, post-exercise repair and remodeling of skeletal muscle proteins provide the
basis for training-induced adaptations that underpin increments in exercise performance. Dietary proteins may augment muscle
repair by providing the *building blocks* (i.e. amino acids) for a positive protein synthesis balance to induce muscle repair following
acute damage. Although many studies support the importance of sufficient protein ingestion in relation to resistance-type exercise
for enhancing muscle mass and reducing muscle soreness, the role of protein supplementation for muscle repair and to reduce
muscle soreness among endurance athletes has been less well studied.

Study objective

The primary aim of the study is to compare the effects of protein versus placebo supplementation on 24 hour post-race delayed onset muscle soreness after strenuous endurance exercise performance among endurance runners. The secondary aim of the study is to compare the effects of protein versus placebo supplementation on post-race muscle damage biomarker concentrations after strenuous endurance exercise performance among endurance runners.

Study design

This double-blind randomized placebo-controlled trial will consist of 2 study arms. The effects of 15 km running exercise on muscle soreness and muscle damage will be examined in two groups: I) protein group (60 g protein per day for 3 days), II) placebo group (isocaloric placebo).

Intervention

Participants will be randomly allocated to one of the two groups. Participants will be instructed to ingest the protein or placebo supplement: 1) directly after finishing the running event, 2) prior to sleep at the same day, 3) during breakfast on the next three days, and 4) prior to sleep on the next two days.

Study burden and risks

The risks involved in participating in this experiment are low. Protein and placebo supplements will be produced under Good Manufacturing Practices in

certified facilities and using approved and commercially available ingredients. Withdrawal of a venous blood sample 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. Furthermore, participants will be asked to fill out questionnaires. The total burden of these measurements is, physically as well as in time, relatively low and results in important information necessary to answer our research question.

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

- Between 30 and 60 years of age
- Registered for the 2018 Seven H ills Run (Zevenheuvelenloop)

- Able to understand and perform the study procedures

Exclusion criteria

- Muscle sorene ss and muscle complaints in daily life (unrelated to exercise) upon enrolment
- Type I or type II diabetes
- Allergic or sensitive for milk proteins, eggs and soybeans, or lactose intolerant.
- Having been diagnosed with intestinal diseases, which will influence the uptake of protein (i.e. active inflammatory bowel disease, Crohn*s disease)
- Having been diagnosed with renal insufficiency
- Use of statins

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-11-2018
Enrollment:	416
Type:	Actual

Ethics review

Approved WMO

Date:	09-10-2018
Application type:	First submission

Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	09-11-2018
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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: 22476
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67354.072.18
OMON	NL-OMON22476

Study results

Date completed:	28-08-2019
Actual enrolment:	323