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

Published: 09-10-2018 Last updated: 15-05-2024

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...

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

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### 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

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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

Interventional
Parallel
Randomized controlled trial
Double blinded (masking used)
Placebo
Treatment

### Recruitment

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

# **Ethics review**

Approved WMODate:09-10-2018Application type:First submission

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Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO	00.11.0010
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
ССМО	NL67354.072.18
OMON	NL-OMON22476

# **Study results**

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