Protein for muscle recovery after exercise

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To assess whether whey protein supplementation during the days before and after muscle-damaging eccentric exercise improves recovery of muscle strength, compared to placebo?Secondary objective(s) are: To assess whether whey protein supplementation...

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

Summary

ID

NL-OMON45952

Source
ToetsingOnline

Brief title
PRIME

Condition

- Other condition

Synonym
muscle damage, muscle function, muscle soreness

Health condition

spierschade na fysieke inspanning

Research involving
Human

Sponsors and support

Primary sponsor: NIZO food research B.V.
Source(s) of monetary or material Support: FrieslandCampina Nederland B.V. (via Stichting Kernhemfonds),Subsidie van Provincie Gelderland in het kader van een consortium project (Eat2Move);Stichting Kernhemfonds (een door de Nederlandse zuivelindustrie opgerichte stichting die onderzoek bij NIZO ten behoeve van de Nederlandse zuivelindustrie co-financiert)

Intervention

Keyword: muscle damage, muscle recovery, muscle soreness, whey protein

Outcome measures

Primary outcome

Change in muscle strength of the quadriceps muscles (isokinetic Maximal

Voluntary Contraction (MVC)) up to 3 days after eccentric exercise, compared to

pre-exercise strength.

Secondary outcome

* Isometric MVC

* Jump height assessed by vertical countermovement jump.

* Thigh circumference.

* Delayed onset muscle soreness (DOMS) assessed by VAS (100 mm)

* Muscle soreness assessed by a 7 point Likert-scale for retrospective pain.

* Muscle tenderness assessed by a manual muscle myometer.

* Rated perceived exertion (RPE), assessed by the BORG scale.

* Plasma creatine kinase (CK) concentrations

* Plasma intestinal fatty acid binding protein (I-FABP) concentrations

* Circulating neutrophils and monocytes (white blood cell count) in whole blood

* Plasma concentrations of IL-6, MCP-1, IL-1ra, IL-8 and IL-10

* Plasma concentrations of NGF

Study description

Background summary

Delayed onset muscle soreness (DOMS) develops 24-48 hours after strenuous exercise biased toward eccentric (muscle lengthening) muscle actions. Soreness is accompanied by a prolonged strength loss, a reduced range of motion, and elevated levels of muscle damage markers in the blood. Reported study results are not consistent with respect to the acute benefits of protein supplementation on reductions in muscle damage and enhanced recovery of muscle function. We hypothesize that supplementation with whey protein is efficacious in improving recovery following eccentric exercise when given in a daily dose of 60 gram in the days before and after the exercise. Reduction of muscle soreness is likely to stimulate people to remain active, and thereby to improve their physical condition and support healthy aging.

Study objective

To assess whether whey protein supplementation during the days before and after muscle-damaging eccentric exercise improves recovery of muscle strength, compared to placebo?
Secondary objective(s) are:
To assess whether whey protein supplementation before and after muscle-damaging eccentric exercise reduces
* muscle soreness?
* blood markers of muscle damage?
* blood markers of inflammation and immune response?

Study design

Double-blind placebo controlled cross-over intervention study.

Intervention

Volunteers will consume either a whey protein supplement (60 g protein/d) or an isocaloric placebo supplement (maltodextrin), additional to their habitual diet, during 9 days. A dose of 20 g protein will be consumed in the morning, between breakfast and lunch, and a dose of 40 g protein will be consumed in the evening.

Study burden and risks

Participants will visit the exercise lab 6 times. Overall, 9 blood samples will be drawn (of which 6 at one visit, via a canula). Participants will have to perform an exhaustive jump test, which is meant to induce moderate muscle damage and muscle soreness. Muscle function tests will be done 6 times (of which 3 at one visit). Volunteers will have to complete an online 24h diet recall over 4 days, and adhere to dietary restrictions and wear an accelerometer during the 9-day intervention period. Test products are commercially available, food-grade food ingredients that are safe in the amounts consumed in this study.

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

* Male

* Age *18 and *35 years.
* BMI *18.5 and *27.5 kg/m2
* Healthy as assessed by the NIZO lifestyle and health questionnaire.
* Recreationally active, defined as performing physical activities on a recreational basis for a maximal duration of 5 hours per week.
* Veins suitable for cannulation (blood sampling)
* Having given written informed consent

Exclusion criteria

* Having a history of medical or surgical events that may significantly affect the study outcome, to be decided by the principal investigator
* Participating in resistance exercise or exercise with a major eccentric component (e.g. (trail) running, football, volleyball, basketball, track and field) in the last 6 months.
* Regular use of the following medication: corticosteroids, antihistamines, NSAID
* Smoking
* Regular use of protein supplements
* Mental status that is incompatible with the proper conduct of the study
* A self-reported reported lactose intolerance, allergy or sensitivity to dairy ingredients
* Evidence of current excessive alcohol consumption (>21 units/week) or drug (ab)use, and not willing/able to stop this during the study.
* Reported slimming or medically prescribed diet
* Participation in any clinical trial including blood sampling and/or administration of substances up to 30 days before Day 01 of this study
* Recent blood donation (<1 month prior to Day 01 of the study)
* Personnel of HAN, NIZO or FrieslandCampina, their partner and their first and second degree relatives

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):	18-02-2019
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-12-2018
Application type:	First submission
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: 27140
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68027.072.18
OMON	NL-OMON27140