The effects of protein ingestion to maximize endurance-based training adaptations in untrained healthy young men

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43095

Source
ToetsingOnline

Brief title
Protein supplementation and endurance-based training adaptations

Condition

- Other condition

Synonym
Not applicable

Health condition

Effect van duurtraining en eiwit op spier en bloed

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Adaptation, Endurance, Muscle, Protein

Outcome measures

Primary outcome

VO2max (maximal oxygen consumption during exercise)

Secondary outcome

Time trial (bicycle ergometer)

1RM strength (1RM leg press / Bio-dex)

Quadriceps cross sectional area (MRI)

Whole body and regional body composition (DXA-scan)

Muscle fibre type specific distribution (muscle biopsy)

Mitochondrial mass (muscle biopsy)

Mitochondrial function (muscle biopsy)

Haemoglobin mass (blood)

Cardboxyhaemoglobin (blood)

Haematocrit (blood)

Red blood cell volume (blood)

Plasma volume (blood)

Body mass index (BMI)

Waist circumference

Leg volume

Study description

Background summary

Physical training can be roughly divided into endurance training and strength training. Regular endurance training provides an improvement of uptake of oxygen by the blood, an improvement in the transport of blood and, finally, a better use of oxygen by the active muscles. Regular strength training on the other hand, allows for improved control of the muscles, growth in the size of the muscles and strengthening of the muscles.

Nutrition plays an important role before, during and after exercise. Carbohydrates are best known for the role they play in the rapid release of energy during exercise, protein and is mainly known for its role in muscle

recovery after exercise. Previous research has shown that protein supplementation optimizes the recovery of strength resulting in bigger and stronger muscles. For endurance training, however, it is currently unclear whether protein supplementation does improve recovery over a longer period (12 weeks).

Study objective

The primary aim of this study is to examine the beneficial effects of additional dietary protein supplementation on the endurance-based exercise training-induced changes in VO2max, endurance performance, muscle strength, body composition, mitochondria, muscle proteins and blood in healthy untrained young men. For a comprehensive insight into the potential underlying mechanisms of the intervention effects on whole body-, muscle- and myocellullar level, a broad range of tests will be performed before, during, and after the intervention period. We hypothesize that additional protein ingestion, on both training and non-training days, during a 12 week endurance training program further increases VO2max, endurance performance and type I muscle fibre cross sectional area when compared to the placebo group.

Study design

This study will be a double blind, randomized, placebo-controlled intervention trial. The total study consists of a screening and an experimental part in which we will focus on the effects of an exercise intervention program with nutritional support on central and peripheral function and exercise performance in untrained healthy young men. We will assess the effects of a 12 weeks endurance-based training program (3x/wk) with or without additional protein supplementation on endurance-based training-induced changes in VO2max, type I and II muscle fibre size, body composition, substrate metabolism and muscle and exercise performance in healthy untrained young men.

Intervention

Three times a week endurance training, for a total period of 12 weeks.

Each training session lasts approximately 60 minutes.

Group Intervention: protein supplement (30 g protein). After training and before bedtime.

Placebo Group: carbohydrate supplement (30 g carbohydrate). After training and before bedtime.

Study burden and risks

Testing effort for maximum endurance and strength:
Exercise testing can lead to muscle soreness. This is harmless and after a few days away.

Infusion needle:
Despite the fact that the blood will be taken with a lot of care and conducted by an experienced nurse, it is possible that by the puncture and the placement of the infusion, bruising occurs.

Muscle biopsy
A muscle biopsy is a small procedure in which a small piece of muscle is removed from the thigh. The muscle biopsy is taken from the right thigh. The skin and the underlying tissue are locally anesthetized. After this, there is provided a small incision (0.5 cm) made in the skin and the muscle sheath. Through this slice of a hollow needle is inserted with which a few chunks of muscle to be disconnected. After taking the muscle biopsy of the wound edges are closed with a sterile bandage and a pressure bandage to minimize the chance of bleeding. The incision will heal completely, but, in some cases, keep subjects a little scar here on. There are small risks associated with taking a muscle biopsy. For example, there is a small risk of a hematoma at the end of the muscle biopsy, in order to counteract the hematoma additional pressure connection will be made. It may also happen that a subject suddenly feel unwell while taking or after the muscle biopsy and that the subject will faints.

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 between 18 and 30 years of age
* BMI between 18.5 * 25 kg/m2
* VO2max 50 of lager
* Recreationally active, performing sports on a non-competitive basis
* Willing to give muscle biopsies
* Willing to give blood samples
* No use of antibiotics in the past month
* No use of illicit drugs
* Suitable veins for blood withdrawal
* Registered by a general-practitioner
* Consumption of alcohol beverages is less than 21 per week
* No blood donor during the study
* Able to be present and all university visits
* Able to perform three exercise sessions weekly for 12 weeks
* Not employed, or intern, or working on thesis at the department of Human Nutrition at Wageningen University
* Not participating in another scientific study (except EetMeetWeet)
* Able to participate during the experimental days en pre tests

Exclusion criteria

* Medical condition that can interfere with the study outcome (i.e. cardiovascular disease, pulmonary disease, lactose and gluten intolerance)
* Use of medications known to interfere with selected outcome measures (i.e. statins, fenofibrate)
* Use of antithrombotic therapy (marcoumar, sintromitis, clopidogrel and NOAC*s).
* Diagnosed with liver disease
* Diagnosed diabetes mellitus type 1 or 2
* (Chronic) injuries of the locomotor system that can interfere with the intervention
* Participants with a recent history or current state of COPD

* Participants with a recent history or current state of rheumatoid arthritis
* Participants with a recent history or current state of musculoskeletal/orthopedic disorders
* Participants with a recent history or current state of renal disorder
* Participants with a recent history or current state of cognitive impairment
* Participants with orthopedic metal implants in the spine and/or upper/lower extremities
* Participants with lactose intolerance and/or dairy protein allergy
* Participants who are enrolled in an interventional biomedical research project or have received an investigational new drug or product with the last 30 days prior to screening.
* Participants on medication, including anticoagulants

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	44
Type:	Anticipated

Ethics review

Not approved

Date:	29-10-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL59021.081.16