# Protein supplementation to augment the training adaptations to endurance-type exercise training.

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Primary Objective: The primary objective of the current study is to assess the impact protein supplementation during long-term endurance-type exercise training on VO2max. Secondary Objective(s): The secondary objective of the current study is to...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Other condition |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45348

**Source**
ToetsingOnline

**Brief title**
Protein and endurance exercise

### Condition

- Other condition

**Synonym**
muscle function, oxidative capacity

**Health condition**

inspanningscapaciteit

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Hogeschool van Arnhem en Nijmegen
**Source(s) of monetary or material Support:** FrieslandCampina

## Intervention

**Keyword:** exercise, nutrition, protein, VO2max

## Outcome measures

### Primary outcome

Maximal oxygen uptake (VO2max): VO2max will be assessed by indirect calorimetry during an incremental exercise prototocol on a cycling ergometer (indirect calorimetry).

### Secondary outcome

Exercise performance: Exercise performance will be assessed by a 10 km time trial.

Muscle function: Maximal strength and muscular endurance will be assessed by isokinetic dynamometry.

Body composition: Whole body and regional body composition will be assessed by a DXA scan and by skinfold measurements according to ISAK standards (International Society for the Advancement of Kinanthropometry).

Hematological and biochemical variables (blood): complete blood count, ferritin, CRP, and markers of bone and joint health.

Mitochondrial function: Mitochondrial function will be assessed in peripheral

blood mononuclear cells (PBMCs)

# Study description

### Background summary

Although many studies support the importance of protein supplementation in relation to resistance-type, the role of protein supplementation in relation to adaptations to endurance exercise training has been less well studied. In this regard, it has been shown that supplementation of protein following endurance exercise accelerates skeletal muscle recovery. Moreover, the results from two small studies suggested that protein supplementation augments the training adaptations to longer term endurance exercise training. More research is required to firmly establish the impact of protein supplementation during long-term endurance exercise training on VO2max and related exercise performance outcomes.

### Study objective

Primary Objective: The primary objective of the current study is to assess the impact protein supplementation during long-term endurance-type exercise training on VO2max.

Secondary Objective(s): The secondary objective of the current study is to assess the impact protein supplementation during long-term endurance-type exercise training on endurance exercise performance (time trial) and muscle function (isokinetic dynamometry).

### Study design

Double blind, randomized, placebo-controlled intervention trial. The study involves 12 weeks of endurance-type exercise training with pre- and post-measurements of exercise capacity and performance. During the 12-week exercise programs, participants will be randomly assigned to a protein or placebo supplement group.

### Intervention

Exercise training: During the 12-week exercise training program participants will complete three exercise sessions weekly. In the training programs continuous endurance exercise sessions will be alternated with interval exercise sessions.

Protein supplementation: All participants will be randomly assigned to the protein or placebo (isocaloric carbohydrate) group. The protein or placebo supplements will be ingested after each training session and each day before sleep.

**Study burden and risks**

During a 12-week periods, subjects perform three endurance exercise sessions per week. The time investment associated with the endurance exercise training is approximately 3 hours per week. The protein supplements and placebos are almost identical to commercially available dairy products. Moreover, the applied doses for the protein supplement and carbohydrate placebo fit within a healthy diet. The protein and placebo supplements will be produced by FrieslandCampina under strict food safety regulations.

The study comprises various measurements with a low risk for complications:
-Participants will perform various exercise tests (VO2max, time trial, isokinetic dynamometry) before and after the 12-week exercise training program. Although the exercise test can be considered as strenuous exercise, the burden is limited to temporary discomfort and muscle soreness.
-Body composition will be assessed twice by DXA. The measurement is painless, non-invasive and involves only low radiation exposure (<10 *Sv).
-Venous blood will be collected twice. For this procedure, a small needle will be inserted into the antecubital vein and blood (25 mL) will be collected through a closed system attached to the needle. The discomfort of this procedure is transient and is comparable to having an injection by a needle, or donating blood.
-A wrist-worn physical activity monitor will be worn twice for period of 7 days period for 24h/day. This measurement is comparable with wearing a watch.
-The 24-hour dietary recalls will collected by the *Compl-eat** software program. This program developed by Wageningen University guides participants through foods and drinks consumed during the previous day. A single 24-h recall takes approximately 30 to 45 minutes to complete. Three 24-h recalls will be conducted before, during and at the end of the 12-week intervention period.

Despite the time investment associated with the exercise training and measurements, this study will give us novel information on the potential impact of protein supplementation on training adaptation to long-term endurance-type exercise training, including VO2-max, exercise performance, and muscle function. As such, this study may identify a novel nutritional strategy to enhance endurance exercise capacity and performance. As we include relatively young and untrained male volunteers, the results will be primarily applicable to this population. Nevertheless, this study may provide a proof-of-principle for populations aiming to maximize the benefit from endurance-type exercise programs, such patients revalidating form myocardial infarction, COPD patients, elite athletes or athletes recovering from injury.

# 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 40 years of age
BMI between 18 * 30 kg/m2
Untrained or recreationally active (i.e. performing sports on a non-competitive basis for a maximal duration of 6 hours per week).
VO2max *50 ml/kg/min
Willing to give blood samples
Able to be present at required test days
Able to perform three exercise sessions weekly for 12 weeks

### Exclusion criteria

Blood donation during the study period
Lactose intolerance and/or dairy protein allergy
Consumption of >21 alcoholic beverages per week
Use of illicit drugs
Use of antibiotics in the past month
Medical condition that can interfere with the study outcome (i.e. cardiovascular disease, pulmonary disease, rheumatoid arthritis, orthopedic disorders, renal disease, liver disease, diabetes mellitus, inflammatory disease, cognitive impairment)
Use of medications known to interfere with selected outcome measures (i.e. statins, fenofibrate, beta-blocker, corticosteroids)
(Chronic) injuries of the locomotor system that can interfere with the intervention
Current participation in other biomedical research study.

## Study design

### Design

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

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 14-05-2017 |
| Enrollment: | 60 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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| Date: | 23-05-2017 |
| 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: 21476
Source: NTR
Title:

## In other registers

| Register | ID |
|---|---|
| CCMO | NL60980.072.17 |
| OMON | NL-OMON21476 |