The effects of additional protein intake on muscle strength and physical performance in physically active elderly

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23080

Source
Nationaal Trial Register

Health condition

sarcopenia, frailty, loss of muscle mass, strength and functionality

sarcopenie, fragiliteit, verlies aan spiermassa, kracht en functionaliteit

Sponsors and support

Primary sponsor: Radboudumc Nijmegen, Netherlands

Intervention

Outcome measures

Primary outcome

Change in maximal voluntary contraction (3 repeated measures (RM) leg extension strength test) and physical performance (SPPB) will be our primary outcome measures.

Secondary outcome

Secondary study parameters are changes in:

o Muscle contractile function*

o Handgrip strength and microFET (dynamometer)

o Timed up-and-go (TUG)

o Anthropometrics

o Body composition (DEXA)

*Performed in a subgroup of 60 subjects (30 intervention, 30 placebo)

Other parameters are:

o Physical fitness (Åstrand-Rhyming test)

o Physical activity (SQUASH) and exercise training (diary)

o Daily dietary and protein intake (two 24h-recalls + FFQ)

o Compliance (protein supplementation)

o Blood analyses

o Urine analyses

o Medical history questionnaire

o Questionnaire screening sarcopenia (SARC-F)

o Questionnaire quality of life (EQ5D)

o Questionnaires muscle complaints (Short-Form McGill Pain Questionnaire (SF-MPQ) and Short-Form Brief Pain Inventory (BPI-SF))

Study description

Background summary

Rationale: Sarcopenia is defined as the age-related loss of skeletal muscle mass, muscle strength and muscle function. These declines can lead to a decrease in physical performance, decreased independence and enhanced vulnerability, and subsequently increased health

care costs. Previous studies have shown beneficial effects of enhanced protein intake in frail elderly but little is known about the effect of enhancing protein intake in currently healthy physically active elderly. It has been shown that physically active elderly have the same age-related declines in muscle strength as their inactive peers, while protein recommendations are often not met in both groups.

Objective: The present study has been designed to investigate the impact of additional protein intake on muscle strength and physical performance in physically active elderly.

Study design: The proposed intervention is a 13-week double-blind randomized placebo-controlled trial with 2 arms. The effects of daily protein supplementation (2x 15g provided at breakfast and after exercise or on days without exercise: at lunch) on muscle strength and physical performance will be investigated.

Study population: The study population includes in total 120 subjects, aged 65 years and above with a protein intake in the lowest quartile and registered to participate in the Nijmegen Four Days Marches 2017.

Intervention (if applicable): The physically active elderly subjects will be randomly assigned to the intervention or control group, receiving either protein supplementation (30 gram per day) or placebo. It will be assured that baseline protein intake, gender and age is similar between the groups. The daily supplementation consists of a protein product (30 grams of protein) or an placebo (consisting of carbohydrates). It will be given in the form of 2 drinks that need to be consumed during breakfast and after exercise (or on days without exercise, during lunch).

Main study parameters/endpoints: The primary outcomes are differences in change in muscle strength and physical performance between the intervention and control group after 12 week intervention. Changes in muscle mass and total body composition, muscle, joint and bone markers and questionnaires changes will also be assessed. Furthermore, during the Four Days Marches we will assess differences between the protein-supplemented group and the placebo group in recovery of physical performance and muscle strength and in biomarkers (inflammation, muscle, joint and bone health).

Study objective

We hypothesize that the ingestion of an additional amount of dietary protein (2 x 15g per day) will increase muscle strength and physical performance in physically active elderly (≥ 65 yrs). Moreover, we hypothesize that the ingestion of additional protein in physically active elderly will have a beneficial effect on recovery of muscle and joint characteristics during the Four Days Marches.

Study design

change in maximal voluntary contraction: 2 time points

Change in SPPB: 4 time points

Intervention

Protein supplements will be provided as ready-to-drink products of 250 ml containing 15 gram protein (MPC-80) and will be produced by FrieslandCampina. De placebo supplements will be provided as ready-to-drink products of 250 ml and will be produced by FrieslandCampina. The products will be vanilla flavoured. Caloric content is very similar between the products. The products will be consumed twice a day for 13 weeks.

Contacts

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Eligibility criteria

Inclusion criteria

- 65 years or older

- Registered for the Nijmegen Four Days Marches 2017

- Protein intake less than 1.0 g/kg bw/d based on FFQ

- Able to understand and perform the study procedures

Exclusion criteria

- Type I or type II diabetes

- Allergic or sensitive for milk proteins, or lactose intolerant.

- Having diagnosed COPD

- Currently treated for cancer

- Having diagnosed renal insufficiency (eGFR<30 (ml/min*1.73m2))

- Having diagnosed intestinal diseases influencing the uptake of protein (i.e. active inflammatory bowel disease, Crohn’s disease)

- Use of statins

- Involved in a heavy resistance type exercise program within the last 2 yrs

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-03-2017
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion
Date: 10-03-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 45732
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6313
NTR-old	NTR6488
CCMO	NL60137.072.16
OMON	NL-OMON45732

Study results