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

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

Summary

ID

NL-OMON45732

Source
ToetsingOnline

Brief title
Prowalking

Condition

- Other condition
- Musculoskeletal and connective tissue disorders NEC

Synonym
Muscle strength loss, reduced phyiscal functionality

Health condition

sarcopenie

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Campina,FrieslandCampina

Intervention

Keyword: Elderly, Muscle strength, Physical performance, Protein

Outcome measures

Primary outcome

The primary outcomes are differences in change in muscle strength and physical performance between the intervention and control group after 12 weeks.

Moreover, muscle mass will be determined to assess differences between the intervention and control group.

Primary outcome

Maximal voluntary contraction (leg extension strength) of 3 repeated measures (3RM) and physical performance (determined with Short Physical Performance Battery (SPPB)).

Secondary outcome

During the Four Days Marches we will assess differences between the protein-supplemented group and the placebo-supplemented group for recovery of physical performance, of muscle strength and biomarkers (muscle and joint).

Secondary study parameters are changes in:

o Muscle contractile function*

o Handgrip strength (dynamometer)

o Timed up-and-go (TUG) test

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 (24h-recalls)

o Compliance (protein supplementation)

o Blood analyses (protein, glucose and insulin (for screening diabetes),

creatinin (for screening renal insufficiency), inflammatory biomarkers, joint

markers)

o Urine analyses (protein, inflammatory biomarkers, joint markers)

o Questionnaire screening sarcopenia (SARC-F)

o Questionnaire quality of life (EQ5D)

o Questionnaire muscle and joint pain (Short-Form McGill Pain Questionnaire

(SF-MPQ) and Brief pain inventory vragenlijst (BPI-SF))

Study description

Background summary

Sarcopenia is 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 active elderly. It has been shown that 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.

Study objective

Therefore the present study is designed to investigate the impact of additional protein intake on muscle strength and physical performance in physically active elderly. Moreover, muscle mass will be determined. Furthermore, we assess the influence of the protein supplementation on the physical performance and muscle and joint health during the Four Days Marches.

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) on muscle strength and physical performance will be investigated.

Intervention

The elderly will be randomly divided into the protein or placebo group. The daily supplementation consists of a protein product (30 grams of protein) or a 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).

Study burden and risks

The risks involved in participating in this experiment are minimal. Stukje tekst over eiwitsupplement Most procedures do not involve any risks for the subjects. The only measurements with a limited burden are blood sampling, muscle contractile function and the DXA scan. 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, the electrostimulation of the quadriceps muscle might feel unpleasant, despite the low force that is generated (30% of the maximal voluntary contraction). Finally, the radiation dosage of a DXA-scan is 4.2 µSv, which is not associated with any health risk.

Contacts

Public
Radboud Universitair Medisch Centrum

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL
Scientific
Radboud Universitair Medisch Centrum

Philips van Leijdenlaan 15
Nijmegen 6525 EX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- 65 years or older
- Registered for the Nijmegen Four Days Marches 2017
- Protein intake less than 1.0 gram/kilogram bodyweight/day
- Able to understand and perform the study procedures

Exclusion criteria

- Type I or type II diabetes (fasted blood glucose level *7,0 mmol)
- Allergic or sensitive for milk proteins, or lactose intolerant.
- Having diagnosed COPD or treatmet with cancer
- Having diagnosed renal insufficiency

- 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2017
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	09-03-2017
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: 23080
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60137.072.16
OMON	NL-OMON23080