The effects of resistance type exercise training and protein supplementation on skeletal muscle mass, strength, and muscle characteristics in healthy elderly men and women

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The main objective of this study is to examine the effects of resistance type exercise training combined with nutritional support on body composition and muscle characteristics in healthy elderly men and women.

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

Summary

ID

NL-OMON36424

Source
ToetsingOnline

Brief title
The effect of resistance training and protein supplementation in elderly.

Condition

- Other condition
- Muscle disorders

Synonym
loss of muscle mass, sarcopenia

Health condition

veroudering

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: TIFN

Intervention

Keyword: muscle mass, protein, resistance training, sarcopenia

Outcome measures

Primary outcome

Muscle fiber cross-sectional area (muscle biopsies)

1RM strength

Quadriceps cross-sectional area (CT scan)

Secondary outcome

Whole body and regional body composition (DXA scan)

Glucose homeostasis and insulin sensitivity (from OGTT / fasting blood samples)

Cognitive function

Study description

Background summary

Aging is associated with several age related changes. One of these changes that happens during aging is the loss of muscle mass. This loss can lead to a decrease in performace, decreased ability to live independently, increased risk for type 2 diabetes, obesity, cardiovascular disease, osteoporosis. The decrease in portein synthesis in elderly people is a main cause for the decrease in muscle mass and muscle function in elderly people.
The most effective way to stimulate and increase muscle protein synthesis is exercise, especially resistance exercise.
The increase in protein synthesis after resistance training will eventually lead to an increase in muscle mass and muscle strength. In this way the

increase in protein synthesis will prevent to some extent the muscle loss observed in the elderly.
For resistance training to effectively stimulate muscle protein synthesis it is necessary that there is enough protein available in the body to increase muscle mass and muscle strength. This is why the intake of proteins is very important. It is not clear yet whether there are extra proteins necessary and if this can lead to a faster growth of muscle mass and muscle strength. In the present study we want to examine the effects of resistance type exercise training combined with nutritional support on body composition and muscle characteristics in healthy elderly men and women.

Study objective

The main objective of this study is to examine the effects of resistance type exercise training combined with nutritional support on body composition and muscle characteristics in healthy elderly men and women.

Study design

In this study we compare 2 groups during 24 weeks. During these 24 weeks the subjects follow a resistance training program, 3 days a week (monday, wednesday and friday). During these 24 weeks the subjects consume a beverage on a daily basis. One group receives the protein beverage and the other group receives the placebo beverage. Muscle fiber cross-sectional area, 1RM strength, quadriceps cross-sectional area will be compared at 0, 12 and 24 weeks time of the intervention.

Intervention

The intervention period is 24 weeks. During these 24 weeks the subjects receive a protein supplement on a daily basis (15g protein) or a placebo bevarage. All subjects will follow a resistance training program during these 24 weeks on monday, wednesday and friday.

Study burden and risks

At the site of the catheter a hematoma could occur. This is the same for the muscle biopsy. The muscle biopsy is performed by an experienced physician. The incision made for obtaining the muscle biopsy will heal completely.
An ECG will be performed, during rest and exercise, before inclusion in the study population, this to exclude cardiovascular problems. The level of radiation emitted during a DXA scan is very low, so this is harmless.
The radiation from the CT scan is negligible because only one image is taken and this on 0, 12 and 24 weeks of the intervention.
The ingested bolus of glucose is comparable with a commercial sport nutrition drink. The ingested proteins are part of a normal diet and impose no risk. To

minimize the risk for muscle soreness and/or muscle injuries, an experienced investigator will supervise all exercise tests and training sessions.

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

Healthy elderly men and women between 65 - 90 years of age

Exclusion criteria

cardiovascular disease, COPD, Parkinson, rheumatoid arthritis, musculoskeletal/orthopaedic disorders, cognitive impairment, lactose intolerance, milk protein allergy as well as subjects

with metal implants will be excluded.

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:	Recruitment stopped
Start date (anticipated):	19-04-2010
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	11-11-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	25-02-2010
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-08-2011
Application type:	Amendment

Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT01004588
CCMO	NL29605.068.09