The influence of leucine supplementation and resistance training on body composition and muscle characteristics in healthy elderly.

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

Summary

ID

NL-OMON29849

Source
ToetsingOnline

Brief title
Leucine and resistance training in healthy elderly.

Condition

- Other condition

Synonym
sarcopenia

Health condition

spierafname door veroudering (sarcopenie)

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Body composition, Leucine, Muscle characteristics, Resistance training

Outcome measures

Primary outcome

Body composition, muscle caracteristics and muscle function will be compaired

before and after interventions.

Secondary outcome

Plasma glucose responses will be compaired before and after interventions.

Study description

Background summary

Ageing is accompanied with a reduced muscle protein synthesis, which is an important cause of the strong decline in skeletal muscle mass and function. This process results in a reduction in physical performance, a loss of functional capacity and an increased likelihood of developing type 2 diabetes, obesity, osteoporosis and cardiovascular diseases in elderly.

The most effective stimulus for muscle protein synthesis is physical activity, especially resistance training. However, for resistance exercise to be effective (i.e. resulting in net protein accretion), the sufficient availability of amino acids as precursors seems to be a decisive determinant. Therefore, post-exercise protein intake is an important factor.

There is also evidence that ingestion of additional leucine, a precursor of proteins, can result in an increased muscle mass and function without physical activity.

Study objective

In part A, we study the influence of ingestion of additional leucine on body composition, muscle function and plasma glucose responses.

In part B, we study the influence of the timing of post-exercise protein intake on the effectiveness of the exercise intervention.

Study design

In part A, 2 groups of healthy elderly will perform a 12 week placebo controlled trial with 2.5 g additional leucine or placebo supplementation per meal.

In part B, 2 groups of healthy elderly will perform a 12 week resistance training program (3 times/week) combined with nutritional supplementation provided either immediately or 2 hours after each exercise session.

In both parts, body composition, muscle function and plasma glucose responses will be compaired before and after intervention.

Intervention

Part A is a 12 week placebo controlled trial with 7.5 g additional leucine or placebo supplementation daily (2.5 g/meal).

Part B is a 12 week resistance training program (3 times/week) combined with nutritional supplementation provided either immediately or 2 hours after each exercise session.

Study burden and risks

At the site of the catheter a hematoma could occur. This is the same for the muscle biopsy. Muscle biopsy is performed by an experienced physician. The incision made for obtaining the muscle biopsy will heal completely. At the beginning of the resistance training program, muscle soreness could occur.

An ECG will be performed (rest and exercise) before inclusion to the study population, to exclude heart failure.

The level of radiation emitted during a DEXA scan is merely a fraction of that emitted during a regular chest X-ray. The MRI scanner does not apply radiation. As long as no metals are implanted in the body, there is no danger attached to MRI scans.

The ingested bolus of glucose is compairable with a commercial sport nutrition drink. The ingested leucine/proteins are part of the normal diet as a precursor for protein synthesis and impose no risk.

To minimize the risk for muscle soreness and/or muscle injuries, an experienced investigator will supervise all 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 male elderly, between 65 and 85 years old.

Exclusion criteria

Impaired renal or liver function, obesity (BMI > 35), cardiovascular disease, diabetes (type I and II), hypertension, reduced physical performance, metal implants, COPD, Parkinson

disease, rheumatoid arthritis, musculoskeletal/orthopedic disorders, regular aspirin use.

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):	01-11-2006
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	26-09-2006
Application type:	First submission
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
CCMO	NL13957.068.06