The effect of Neuromuscular Electrical Stimulation on post-prandial muscle protein accretion in healthy elderly men

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The aim of this study is to investigate the effect of a single bout of NMES on muscle protein synthesis rates in healthy elderly males.

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

Summary

ID

NL-OMON36866

Source
ToetsingOnline

Brief title
ES-PRO

Condition

- Other condition
- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym
disuse atrophy

Health condition

muscle metabolism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Elderly, Neuromuscular electrical stimulation, Protein intake, Skeletal muscle

Outcome measures

Primary outcome

Muscle protein synthesis rates, expressed as fractional synthetic rate (FSR).

Secondary outcome

Muscle tracer enrichment, digestion and absorption kinetics of a casein drink

influenced by NMES.

Study description

Background summary

With human aging there is a gradual but progressive decline in skeletal muscle mass, termed sarcopenia.. While the underlying cause of sarcopenia is likely to be multifaceted, a primary factor is that elderly individuals frequently experience short periods of muscle disuse following limb immobilization or bed-rest (due to injury or illness) causing rapid muscle loss. Elderly individuals seem to be more susceptible to muscle disuse atrophy and are less likely to fully regain their muscle tissue during subsequent rehabilitation when compared to the young. Muscle loss during a period of disuse is attributed to an impairment of muscle protein synthesis rates. Accordingly, feasible strategies for maintaining muscle protein synthesis rates in elderly individuals, and thus having the potential to attenuate the loss of muscle mass during disuse need to be pursued. Local neuromuscular electrical stimulation (NMES) offers such a potential strategy but, as yet, remains relatively unexplored.

Study objective

The aim of this study is to investigate the effect of a single bout of NMES on

muscle protein synthesis rates in healthy elderly males.

Study design

10 healthy, elderly men will consume a 20g bolus of intrinsically L[13C]phenylalanine labelled casein protein immediately following 70 min of one-legged NMES. Regular blood samples will be collected and muscle biopsies will be obtained immediately prior to protein ingestion and 240 min after ingestion from both legs to determine de novo muscle protein synthesis rates from both the stimulated (STIM) and un-stimulated control (CON) legs.

Intervention

Consumption of a 20g bolus of intrinsically L[13C]phenylalanine labelled casein protein and 70 min of one-legged NMES.

Study burden and risks

The risks involved in participating in this experiment are minimal. Insertion of the catheters in a vein is comparable to a normal blood draw and the only risk is a small local hematoma. This is the same for the muscle biopsies. The incision made for obtaining the muscle biopsy will be done by an experienced physician, following local anesthetics of the skin and muscle fascia, and will heal completely. The test beverages contain intrinsically labeled dietary protein which is safe for human consumption and has been used in previous studies (MEC 11-3-057 and MEC 11-3-088). NMES carries no potential risks other than slight skin irritation from the surface electrodes.

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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 65 - 85 years
18.5 < BMI < 30 kg*m2

Exclusion criteria

- Type II diabetes
- All co morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g. arthrosis, arthritis, spasticity/rigidity, all neurological disorders and paralysis).
- Use of anticoagulants, blood diseases, allergy for lidocain
- Use of NSAIDs and acetylsalicylic acid
- Patients suffering from PKU (Phenylketonuria)
- Presence of implantable cardioverter defibrillator and/or pacemaker
- Performed regular resistance type exercise in the past 6 months
- Use of any tools to assist during walking (cane/ crutches/ walker)
- (Partial) foot/ leg amputation

Study design

Design

Study type:	Interventional
Intervention model:	Crossover

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2012
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Tensmed S84 (neuromuscular electrical stimulation)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	25-07-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	10-09-2012
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	NCT01615276
CCMO	NL40564.068.12