The effect of neuromuscular electrical stimulation on post-prandial protein accretion during the day and prior to sleep

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The aim of this study is to investigate the effect of a single bout of NMES on post-prandial muscle protein accretion during the day and prior to sleep in healthy elderly males.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Protein and amino acid metabolism disorders NEC
Study type	Interventional

Summary

ID

NL-OMON40767

Source ToetsingOnline

Brief title ES-PRO comparison

Condition

- Protein and amino acid metabolism disorders NEC
- Muscle disorders

Synonym loss of muscle mass, Sarcopenia

Research involving Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

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Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: elderly, muscle disuse, neuromusculaire electrostimulatie (NMES), protein feeding

Outcome measures

Primary outcome

De novo muscle protein accretion, measured as enriched muscle protein [mole

percent excess (MPE)].

Secondary outcome

Plasma amino acid enrichment after ingestion of the intrinsically labeled

protein

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. Muscle loss during a period of disuse is attributed to an impairment of muscle protein synthesis rates, especially in the post-prandial phase after a meal. Local neuromuscular electrical stimulation (NMES) has been shown to directly stimulate fasting muscle protein synthesis rates. After that, it has previously been applied in our laboratory in two different settings (i.e. during the day and prior to sleep) in combination with protein intake. From the results of both studies, it seemed that application of NMES during the day was more effective in stimulation muscle protein synthesis than when applied prior to sleep. However, given the relevance of building new muscle protein to hospitalized, and often malnourished, patients, the effect of protein ingestion on skeletal muscle protein accretion should be examined. Therefore, in the current study, we wish to compare the efficacy of both methods in stimulating post-prandial muscle protein accretion.

Study objective

The aim of this study is to investigate the effect of a single bout of NMES on post-prandial muscle protein accretion during the day and prior to sleep in healthy elderly males.

Study design

20 healthy, elderly men will be allocated to 70 minutes of NMES plus 20 g intrinsically L-[13C]phenylalanine labelled casein ingestion during the day (arm 1), or 40 g intrinsically L[13C]phenylalanine labelled casein ingestion prior to sleep (arm 2). Regular blood samples will be collected and muscle biopsies will be obtained immediately prior to protein ingestion and 240 min (arm 1) or 480 min (arm 2) after ingestion from both legs to determine de novo muscle protein accretion from both the stimulated (STIM) and un-stimulated control (CON) legs.

Intervention

Consumption of a bolus of intrinsically L[13C]phenylalanine labelled casein protein and 70 min of one-legged NMES, either during the day or prior to sleep.

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, MEC 11-3-088, MEC 12-3-020, MEC 13-3-024 etc). NMES carries no potential risks other than slight skin irritation from the surface electrodes. Due to the possible risk of DVT in arm 2 of the study, a series of small exercises will be done (to keep the calf pump active) 3 times during the test day.

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

- Age 65-85 years

- Male
- 18.5 * BMI * 30.0

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, paralysis, hip/knee surgery).

- 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	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2015
Enrollment:	28
Туре:	Actual

Medical products/devices used

Generic name:	Neuromuscular Electrical Stimulation
Registration:	Yes - CE intended use

Ethics review

Approved WMO	
Date:	18-12-2014
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

ССМО

ID NL50545.068.14