The effects of daily neuromuscular electrical stimulation during short term one-legged knee immobilization on muscle mass in healthy young men

Published: 08-02-2012
Last updated: 30-04-2024

To investigate the effects of 5 days of one legged knee immobilization with or without daily NMES on quadriceps CSA, lean mass and muscle fiber characteristics.

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

Summary

ID

NL-OMON37432

Source
ToetsingOnline

Brief title
ESDIM

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: Immobilization, Neuromuscular electrical stimulation, Skeletal muscle

Outcome measures

Primary outcome

Primary: Quadriceps CSA

Secondary outcome

quadriceps lean mass, type I and II muscle fiber CSA and SC content, muscle

strength.

Study description

Background summary

Situations such as injury or illness can necessitate a period of muscle disuse (limb immobilization or bed-rest) in otherwise healthy individuals. Even brief periods of such muscle disuse lead to a rapid loss of muscle mass and, consequently, functional strength. Accordingly, feasible strategies for attenuating the loss of muscle during disuse need to be pursued. Local neuromuscular electrical stimulation (NMES) offers such a potential strategy but, as yet, remains untested during muscle disuse in healthy humans.Therefore, the aim of the present study is to investigate whether twice daily local (quadriceps) NMES attenuates muscle loss during 5 days of one legged knee immobilization.

Study objective

To investigate the effects of 5 days of one legged knee immobilization with or without daily NMES on quadriceps CSA, lean mass and muscle fiber

characteristics.

Study design

Randomized, parallel (two groups) study design.

Intervention

Five days of knee immobilization with or without twice daily NMES.

Study burden and risks

The risks involved in participating in this experiment are minimal. Muscle biopsies will be taken through a small (5 mm) incision, following local anesthetics of the skin and muscle fascia, and will heal completely. Muscle biopsies will only be obtained by an experienced physician. Five days of limb immobilization via a knee brace will impair subject*s mobility for this period. However, to minimize any risk of injury subjects will not be allowed to drive a vehicle or ride a bicycle and will have daily contact with the investigators experimenters. The expected loss of muscle mass and strength following immobilization will be rapidly (<2 weeks) regained due to the inclusion of young, healthy volunteers.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 50 - room 2.208
6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 50 - room 2.208
6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male
- Aged between from 18-35 years
- BMI above 18.5 and below 30 kg/m2

Exclusion criteria

- Any family history of thromboses
- All co-morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g. arthritis, spasticity/rigidity, all neurological disorders and paralysis).
- Diagnosed impaired renal or liver function
- Myocardial infarction within the last 3 years
- Use of anti-coagulants

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	08-02-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	02-04-2012
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
CCMO	NL38575.068.11