The impact of short-term bed-rest on skeletal muscle mass and insulin sensitivity in healthy, young men

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To investigate the impact of 7 days of bed-rest on skeletal muscle mass, strength and whole-body insulin sensitivity in healthy, young men.

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

Summary

ID

NL-OMON41776

Source
ToetsingOnline

Brief title
Bed-rest, muscle mass and insulin sensitivity

Condition

- Other condition
- Metabolism disorders NEC
- Muscle disorders

Synonym
disuse atrofie

Health condition

muscle metabolism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: bed-rest, insulin sensitivity, muscle disuse, skeletal muscle

Outcome measures

Primary outcome

Quadriceps muscle cross sectional area (CSA)

Secondary outcome

Whole body insulin sensitivity, whole body lean mass, leg lean mass, lower back

muscle CSA, muscle strength, type I and II muscle fiber CSA and SC content,

mRNA and protein expression of key genes involved in the regulation of muscle

mass.

Study description

Background summary

Admittance to hospital generally leads to a period of whole body disuse (i.e. bed-rest). Prolonged bed-rest causes substantial skeletal muscle loss and subsequent negative health consequences. However, the average length of stay in hospital for acute illness is approximately one week. It is currently unknown what the impact only 7 days bed-rest has on skeletal muscle mass and metabolic health.

Study objective

To investigate the impact of 7 days of bed-rest on skeletal muscle mass, strength and whole-body insulin sensitivity in healthy, young men.

Study design

Single group intervention study with pre and post intervention testing.

Intervention

Seven days of bed-rest.

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. Seven days of bed-rest will impair subject*s mobility for this period but they will be monitored constantly by researchers. There is a risk of DVT, which will be minimized by performing exercises to activate the calf muscle three times daily. Additionally, on days 0, 2, 4, 6 and 7 of bed-rest, additional blood will be collected to determine D-dimers and other coagulation factors, to ensure an accurate and quick response in case of the development of thrombosis. The expected loss of muscle mass and strength following bed-rest will be rapidly (<4 weeks) regained due to the inclusion of young, healthy volunteers.

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

- Male
- Aged from 18-35 years
- 18.5 < BMI < 30 kg/m2
- Recreationally active (performing non-competitive physical exercise at least one time per week for minimally 60 minutes)

Exclusion criteria

- Smoking
- Performing regular resistance training (3+ times per week, carrying out progressive training) in the previous 6 months
- Hypertension (according to WHO criteria) [45] and/or cardiovascular disease
- Any back/leg/knee/neck/postural complaints
- Use of any prescribed medication
- Type 2 diabetes mellitus
- Any family history of thrombosis
- All co-morbidities interacting with mobility and muscle metabolism of the lower limbs (e.g. arthritis, spasticity/rigidity, all neurological disorders and paralysis).
- Myocardial infarction within the last 3 years
- Use of anti-coagulants
- A history of deep vein thrombosis (DVT) in the leg

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):	20-06-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	14-05-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	27-08-2014
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	NCT02109380
CCMO	NL48569.068.14