Assessment of a novel strategy to attenuate muscle mass loss during 2 weeks of bed rest

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

Summary

ID

NL-OMON45252

Source
ToetsingOnline

Brief title
Bed rest & Blood flow restriction

Condition

- Muscle disorders

Synonym
Inactivity, Skeletal Muscle Disuse

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bed rest, Blood flow restriction, Inactivity, Muscle

Outcome measures

Primary outcome

The primary outcome measure is the amount of muscle mass in the legs before and after 2 weeks of bed rest with the application of blood flow restriction.

Secondary outcome

Whole-body skeletal muscle mass

Leg and whole-body lean tissue mass

Quadriceps muscle CSA

Muscle fibre type specific CSA, vascularization and muscle fibre type-specific SC content

Myofibrillar and mitochondrial fractional synthesis rate

Whole-body adipose tissue

Adipose tissue gene expression

Leg muscle and maximal grip strength

Oral Glucose Tolerance

Study description

Background summary

Various cases of injury or illness require hospitalization. Due to the physical inactivity (or muscle disuse) that is associated with this hospitalization, individuals lose muscle mass and strength. The more muscle mass and strength is lost, the longer it takes to recover from this period of hospitalization. Hence it is of utmost importance to minimize the loss of skeletal muscle mass and strength during prolonged periods of inactivity such as bed rest. A potential

strategy to attenuate skeletal muscle mass and strength loss during bed rest is the application of blood flow restriction. This means that, by the temporary inflation of a cuff around the leg, the blood flow to the muscle will be restricted. However, it remains to be elucidated whether this method indeed prevents/attenuates muscle mass and strength loss.

Study objective

In this study we will assess whether the application of daily blood flow restriction during 2 weeks of bed rest will attenuate losses in skeletal muscle mass and strength. With measurements, before, during and after the bed rest period, we can assess the impact of blood flow restriction during inactivity.

Study design

A controlled "within-subjects" design.

Intervention

Applying blood flow restriction during 2 weeks of bed rest.

Study burden and risks

There are not many risks involved in this study. The insertion of the catheter and/or venipuncture for blood draws from a vein in the arm/hand during the different test days may lead to a small, local hematoma. This also applies for the possibility of a hematoma at the biopsy site. The incision made at the biopsy site will close up within two days. The muscle will recover from the biopsy without permanent effects.
Since it is not allowed to perform any weight-bearing activities, the risk for deep vein thrombosis (DVT) is increased. To minimize the risk of DVT, participants are requested to perform an exercise routine which will help to minimize the risk of developing thrombosis three times per day during the bed-rest period. Every small surgical procedure, as well as for instance a venipuncture (blood sample) and a muscle and fat biopsy, can be slightly painful in some cases. In some exceptional cases, taking a muscle biopsy is painful. Hematoma*s, infections etc. are possible but extremely rare. The muscle and fat biopsies will be taken by an experienced physician. Before and immediately after the bed-rest period DEXA- and CT-scans will be performed. The radiation released during the DEXA- and CT-scan in this study will be lower than the background radiation in the Netherlands, which is 2.5 mSV per years, and will cause no risks. MRI has no radiation involved and will also have no risks. However, it is important that participants are not wearing any metals inside and/or outside of your body (e.g., pacemakers, chains, rings etc.) as this might be attracted to the magnet of the MRI device. The labelled water that will be used in this study has been used extensively in previous research

studies and there are no risks involved. One possible, but unlikely, event that might be a result of ingestion of the labelled water is that participants might experience some feelings of dizziness for a short period of time directly after ingestion. However, this is very unlikely in the small dosages that we provide. Finally, it is important to realize that as a consequence of the 14 day bed rest period participants are likely to experience a reduction in muscle mass and strength. Due to the reduction in muscle mass and strength participants are also likely to experience some degree of reduced coordination and/or balance for the first day or two following bed rest. Previous research shows that in only a few weeks, muscle mass, strength and coordination/balance is fully restored.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 60
Maastricht 6229 ER
NL
Scientific
Universiteit Maastricht

Universiteitssingel 60
Maastricht 6229 ER
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy males
Age between 18 and 35 y
BMI between 18.5 and 30 kg/m2

Exclusion criteria

-Smoking
-Type 2 Diabetes Mellitus
-Any back/leg/knee/neck/postural complaints *
-Any history or 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 certain anti-coagulants (use of thrombocyte aggregation inhibitors such as Ascal, *acetylsalicylic acid, aspirin and carbasalaatcalcium is permitted. Use of other thrombocyte aggregation inhibitors will be discussed with the responsible physician) *
-Performing regular resistance training (3+ times per week, carrying out progressive training) in the previous 6 months
-Hypertension (according to WHO criteria) and/or cardiovascular disease
-A history of deep vein thrombosis (DVT) in the leg
-Having donated blood in the 3 months prior to the study

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-07-2017

Enrollment:	19
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2017
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	NL61322.068.17
Other	Wordt nog doorgegeven