Acute intravascular volume transfers during isometric leg exercise

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Quantifying the influence of isometric leg exercise on leg, liver, spleen and if feasible heart volume during modelled orthostatic stress. After this study, the next step will involve taking similar experiments to one of the three upright MRI…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30131

Source
ToetsingOnline

Brief title
Acute intravascular volume transfers during isometric leg exercise

Condition

- Other condition

Synonym
(low) blood pressure, fainting

Health condition

circulatie fysiologie

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Stipendium Nederlandse Hartstichting T007/2004

Intervention

Keyword: exercise, MRI, muscle pump, physiology

Outcome measures

Primary outcome

Volumes of legs, liver, spleen and heart during stages of LBNP with and without

isometric leg exercise.

Secondary outcome

n.a.

Study description

Background summary

Muscle tension in the lower body promotes venous return and tensing of leg muscles increases orthostatic tolerance and can be used to abort an impending vasovagal faint. It's generally accepted that the underlysing mechanism is an increase in thoracic blood volume.

The contribution of muscle tensing to the circulation has been poorly quantified. Earlier studies looked at changes in leg volume during orthostatic stress using traditional plethysmographic methods. CT and MRI have been used for determining changes in leg volume during prolonged supine rest but never have they been used to examine the intracorporal volume shifts, nor during exercise.

Study objective

Quantifying the influence of isometric leg exercise on leg, liver, spleen and if feasible heart volume during modelled orthostatic stress. After this study, the next step will involve taking similar experiments to one of the three

upright MRI scanners available in Europe.

Study design

Eight healthy volunteers will be subjected to an incrementing LBNP challenge while positioned in an MRI scanner. LBNP is a widely accepted model for orthostatic stress. During rest and during isometric leg exercise (retro-flexion in the hip with straightened legs) a scan is made of the legs, abdomen and thorax. Simultaneously blood pressure is continuously non-invasively measured with Finapres. Via pulse wave analysis changes in cardiac output are determined. Cerebral oxygenation is measured by nera-infrared spectroscopy and cerebral blood flow velocity by trans cranial echo-doppler. Off-line changes in leg, liver, spleen and (possibly) heart volume will be related to changes in cardiac output.

Study burden and risks

Risks: pre-syncope complaints during (final stage, 50 tor)LBNP

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

healthy normotensive individuals (age 20-35 yr, BMI 20-25, height 160-190 cm)

Exclusion criteria

-use of any medication that interferes with cardiovascular regulation.
-(suspected) pregnancy or desire to become pregnant in the period of the study
-(suspected) cardiovascular disease
-presence of any circumstance that is likely to interfere with normal orthostatic tolerance and/or the use of LBNP and/or MR-Imaging
-wish not to be informed about significant irregularities from MRI;Students and employees of the AMC can not take part in study.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-04-2006
Enrollment:	8
Type:	Anticipated

Ethics review

Approved WMO
Application type: First submission

Review commission: METC Amsterdam UMC

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	NL11627.018.06