Validation of pelvic Lower Body Negative Pressure Box

Published: 03-09-2015
Last updated: 19-04-2024

Compare the hemodynamic response to pelvic and conventional LBNP and assess head motion.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational non invasive

Summary

ID

NL-OMON42418

Source
ToetsingOnline

Brief title
Validatie pelvic LBNP box

Condition

- Heart failures
- Vascular hypertensive disorders

Synonym
circulation; blood flow

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Rembrandt Institute of Cardiovasculair Science

Intervention

Keyword: lower body negative pressure, orthostatic stress

Outcome measures

Primary outcome

heart rate

stroke volume

head motion

Secondary outcome

blood volume shift

Study description

Background summary

Lower body negative pressure (LBNP) is an othostatic test that can be performed in supine position in an MRI scanner. Application of negative causes the subject to shift downward possible affecting the MRI measurements. Preventive measures, such as a saddle and subject fixation straps, have not been able to sufficiently reduce the motion while remaining comfortable for the subject. We propose a new type of LBNP box that balances the forces on the subject thereby reducing the motion.

Study objective

Compare the hemodynamic response to pelvic and conventional LBNP and assess head motion.

Study design

Observational. Measurements are performed in the Laboratory for Clinical Cardiovascular Physiology (AMC) and take approximately two hours. Hemodynamic parameters (including blood pressure, heart rate and stroke volume), central blood volume (using thoracic impedance measurements) and leg blood volume (using near-infrared spectroscopy (NIRS) and strain-gauge plethymography) will be recorded in rest and during 'lower body negative

pressure'. All measurements will be non-invasive.

Study burden and risks

No benefits and risks are anticipated for the subjects in the study population

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 between 18 and 30 years
Non-smoking
BMI between 18 and 28 kg/m2
Height between 160 and 190 cm

Exclusion criteria

Medical history of CV disease, hypertention, diabetes mellitus, pulmonary disease, neurological disease, malignant disease and/or venous insufficiency (as assessed with a questionnaire)
Smoking, or having smoked less than 10 years ago
Use of systemic medication
Alcohol use of > 3 units per day

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-03-2016
Enrollment:	11
Type:	Actual

Ethics review

Approved WMO

Date:	03-09-2015
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	NL54138.018.15