THE EFFECT OF COMPRESSION STOCKINGS ON SYSTEMIC AND PERIPHERAL PERFUSION PARAMETERS DURING HEAD UP TILT IN HEALTHY VOLUNTEERS

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To study the effect of compression stockings during supine and head up tilt on cardiac stroke volume as a reflection of the changes in central blood volume.

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

Summary

ID

NL-OMON37193

Source
ToetsingOnline

Brief title
Effect of Compression Stockings on Hemodynamics

Condition

- Other condition

Synonym
Compression stocking, hemodynamics

Health condition

hemodynamic

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Compression Stocking, Head up tilt, Hemdynamics

Outcome measures

Primary outcome

Stroke volume, cardiac output, heart rate, arterial blood pressure

Secondary outcome

Tissue oxygen saturation (StO2) and perfusion index (PI)

Study description

Background summary

The head up tilt from supine position is a commonly used maneuver to induce an acute reduction in central blood volume. The reduction of preload leads to a decrease in stroke volume and an increase in heart rate in order to maintain cardiac output and arterial blood pressure. These central hemodynamic alterations are accompanied by vasoconstriction, leading to decreased perfusion of the peripheral circulation. Our hypothesis is that the application of compression stockings on the lower extremities prevents the loss of central blood volume during head up tilt and thereby will help maintain central and peripheral perfusion during this maneuver.

Study objective

To study the effect of compression stockings during supine and head up tilt on cardiac stroke volume as a reflection of the changes in central blood volume.

Study design

Intervention study

Intervention

Volunteers will wear compression stockings on both legs, which will be inflated prior to the head up tilt maneuver from supine position. Stockings will be inflated for 3 minutes during supine and head up tilt to the pressures of 50 cmH2O. Central hemodynamic measurements will be performed non-invasively with Finapres®. Peripheral perfusion will be measured non-invasively with near infrared spectroscopy (NIRS) and finger plethysmography, applied to the thenar and index finger, respectively.

Study burden and risks

We will apply a pressure of 50 cmH2Oto inflate the compression stockings. This pressure has been proven safe, not painful and not to induce ischemia. Since all techniques and measurements are non-invasive , the participating volunteers will not be exposed to additional risks.

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 subjects

Exclusion criteria

- Subjects will be excluded if they are taking cardio-active or neuro-active medications or if they have a history of syncope or orthostatic intolerance.
- Wounds on the lower leg

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-07-2012
Enrollment:	19
Type:	Actual

Medical products/devices used

Generic name:	External leg compression pump (circulatory support device)
Registration:	No

Ethics review

Approved WMO Date:	11-07-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL40523.078.12