Validation of the measurement of venous compliance during orthostatic stress

Published: 12-09-2006 Last updated: 21-05-2024

To determine the best method of measuring venous compliance in women. To determine the influence of orthostatic stress on venous compliance and the best method to measure VC during orthostatic stress.

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

Summary

ID

NL-OMON30045

Source ToetsingOnline

Brief title Venous compliance during orthostatic stress

Condition

- Other condition
- Maternal complications of pregnancy
- Vascular hypertensive disorders

Synonym

elasticity of the vessels, venous compliance

Health condition

fysiologie

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud **Source(s) of monetary or material Support:** Ministerie van OC&W

Intervention

Keyword: orthostatic stress, validation, venous compliance

Outcome measures

Primary outcome

the best method of measurement of venous compliance during orthostatic stress

Secondary outcome

Influence of orthostatic stress on venous compliance

Study description

Background summary

Venous compliance (VC) represents the accommodated amount of volume by raising venous pressure with 1 mmHg. In obstetrics, VC plays an important part. The adaptation to pregnancy requires an increase in VC, which is reduced in women who eventually develop preeclampsia.

In an earlier study, we developed 2 faster methods. However, those methods turned out to have a high coefficient of reproducibility (CR) and coefficient of variance (CV). Another fast method to measure VC is developed by Halliwill et al. In this method cuff pressure is kept at 60 mmHg for 4 minutes, after which the cuff is deflated with 1 mmHg/s. Halliwill also introduced a non-invasive method to measure intravenous pressure. Unfortunately, we expect this method to be inappropriate for applications in the obstetric field, because of the increased capillary leakage in pregnancy and the used cuff pressure of 60 mmHg is possibly not sub-diastolic in (pregnant) women. Therefore, a comparison of these methods is needed to determine the best method of measuring VC in women.

Besides, we would like to study the effect of orthostatic stress on venous compliance and the best method to measure VC during orthostatic stress. We expect a decrease in venous compliance when sympathetic activity increases during head-up tilt. A decrease in venous compliance in this situation will create a sufficient venous return and thus cardiac output.

Study objective

To determine the best method of measuring venous compliance in women. To determine the influence of orthostatic stress on venous compliance and the best method to measure VC during orthostatic stress.

Study design

observational/validation study

Study burden and risks

There is a chance of imminent fainting at (mainly) 60 degrees head-up tilt, which will resolve immediately after changing to supine position. Besides, volunteers can experience irritation of the finger cuff (Finometer) and cuff placed around the upper left arm (plethysmography). The amount of mercury in the mercury-in-Silastic strain includes a negligibly risk for the volunteers.

An intravenous catheter will be inserted in an antecubital vein, which has a small chance of infection and/or haemorrhage on the place of insertion.

Contacts

Public

Universitair Medisch Centrum Sint Radboud

Postbus 9101 6500 HB Nijmegen Nederland **Scientific** Universitair Medisch Centrum Sint Radboud

Postbus 9101 6500 HB Nijmegen Nederland

Trial sites

Listed location countries

Netherlands

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Eligibility criteria

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

Inclusion criteria

age between 18 and 30 years healthy female

Exclusion criteria

hypertension antihypertensive medication orthostatic intolerance

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-06-2006
Enrollment:	10
Туре:	Anticipated

Ethics review

Approved WMOApplication type:First submissionReview commission:CMO regio Arnhem-Nijmegen (Nijmegen)

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 CCMO **ID** NL12416.091.06