Cardiovascular changes during orthostatic stress in women with a vascular complicated obstetric history or recurrent miscarriage

Published: 12-06-2007
Last updated: 14-05-2024

To determine the cardiovascular changes in response to orthostatic stress in women with a vascular complicated obstetric history or recurrent miscarriage.

Ethical review	Approved WMO
Status	Pending
Health condition type	Maternal complications of pregnancy
Study type	Observational non invasive

Summary

ID

NL-OMON30343

Source
ToetsingOnline

Brief title
Orthostatic stress in women with a normal versus low plasma volume

Condition

- Maternal complications of pregnancy
- Vascular hypertensive disorders

Synonym
elasticity of the vessels, venous compliance

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, plasma volume, venous compliance

Outcome measures

Primary outcome

Differences in venous compliance in response to orthostatic stress between

women with a normal and women with a low plasma volume.

Secondary outcome

Differences in response to orthostatic stress between women with a normal and

women with a low plasma volume, regarding sympathetic activity, baroreflex

sensitivity, heart rate, blood pressure, cardiac output, stroke volume and

blood pressure.

Study description

Background summary

A low plasma volume is a common characteristic of women in a pregnancy complicated by preeclampsia1. In more than half these women plasma volume remains subnormal after delivery, without compensatory neurohumoral changes2-4. A chronic lower plasma volume is associated with reduced venous compliance and capacitance5, and a higher resting sympathetic activity and a lower baroreflex sensitivity6, 7.
Functionally, a low plasma volume may affect the venous reserve capacity. Under basal conditions * of the plasma volume is localized in the venous compartment8. About 60% is hemodynamically inactive (unstressed volume) and reflects the venous reserve capacity9. The unstressed volume is mobilized in situations when the demand is increased, such as in physical exercise or during orthostasis.
During exercise, women with low plasma volume demonstrate a reduced ability to raise stroke volume, leaving cardiac output primarily modulated by changes in heart rate10. Therefore, a chronic low total plasma volume most likely primarily affects the unstressed volume and thereby lowers the venous reserve

capacity. This is likely to negatively affect orthostatic tolerance. Postural change induces an initial decrease in venous return, that negatively affects cardiac output. To ascertain adequate venous return, a compensatory increase in hemodynamically active (stressed) volume is needed at the expense of the unstressed volume, through venoconstriction.
In an earlier study (CMO number: 2006/111) we observed a decreasing venous compliance during head-up tilt in healthy female volunteers. However, the response in women with a low plasma volume (and most likely a decreased unstressed volume), is currently unknown.
In this study, we would like to test the hypothesis that normotensive women with a low plasma volume and a history of preeclampsia or recurrent miscarriage exhibit less tolerance to head-up tilt, as indicated altered cardiovascular changes in response to orthostatic stress.

Study objective

To determine the cardiovascular changes in response to orthostatic stress in women with a vascular complicated obstetric history or recurrent miscarriage.

Study design

To minimize any muscular activity, subjects will be stabilized on a comfortable mattress on a tilt table. All participants will be subjected to orthostatic stress with passively changing body posture from 20 degrees head down to 60 degrees head up tilt, in steps of 20* at 10 minutes intervals. Finger blood pressure and heart rate will be measured continuously during the complete experiment by Finometer (Finapres B.V., the Netherlands). From these data, sympathetic activity, baroreflex sensitivity and changes in cardiac output and stroke volume can be determined.
Venous compliance of the left forearm will be measured by strain gauge venous occlusion plethysmography with direct intravenous pressure measurement. An intravenous catheter will be inserted in an antecubital vein and connected to a pressure transducer system. Venous compliance will be measured at each position according to the INCR-method. In this method the cuff will be inflated from 0 to 40 mmHg during 1 minute. During this period, changes in forearm volume are measured by a mercury-in-Silastic strain gauge at 6 cm distal to the antecubital crease. Intravenous pressure is measured by the pressure transducer system.

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 the 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

history of recurrent miscarriage
vasculair complicated obstetric history

Exclusion criteria

hypertension
use of antihypertensive medication

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-12-2006
Enrollment:	170
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review 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	ID
CCMO	NL15417.091.06