Central Hemodynamics, Augmentation index and Microcirculation after Phlebotomy

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27853

Source
Nationaal Trial Register

Brief title
CHAMP study

Health condition

Augmentation index
Central blood pressure
Phlebotomy
Microcirculation
Plasma viscocity

Augmentatie index
Centrale bloeddruk
Aderlating
Microcirculatie
Plasmaviscociteit

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Academisch Medisch Centrum

Intervention

Outcome measures

Primary outcome

The principal endpoint is defined as the difference in AIx (≥4%) before and after phlebotomy while standing.

Secondary outcome

Difference in central BP before and after phlebotomy while standing

• Differences in AIx and central BP before and after phlebotomy while supine

• Differences in AIX and central BP following the effects of counter manoeuvres (leg crossing and thigh compression) before and after phlebotomy while standing

• Differences in stroke volume, heart rate and systemic vascular resistance before and after phlebotomy while supine and after standing

• Differences in forward and backward wave analysis before and after phlebotomy while supine and after standing

• Differences in baroreflex sensitivity before and after phlebotomy while supine and after standing

• Differences in AIx and central BP after phlebotomy and after compensatory saline infusion while supine and after standing

• Differences in stroke volume, heart rate and systemic vascular resistance after phlebotomy and after compensatory saline infusion while supine and after standing

• Differences in forward and backward wave analysis after phlebotomy and after compensatory saline infusion while supine and after standing

• Differences in forward and backward wave analysis after phlebotomy and after compensatory saline infusion while supine and after standing

• Differences in AIX and central BP following the effects of counter manoeuvres (leg crossing and thigh compression) minutes after phlebotomy and after compensatory saline infusion

• Difference in microcirculation before and after phlebotomy with or without volume replacement.

Study description

Background summary

Our principal aim is to assess the effects of phlebotomy on aortic augmentation (AIx) and central BP in supine position and after standing, second, to assess the effects of counter manoeuvres (leg crossing and thigh compression) on aortic augmentation (AIx) and central BP before and after phlebotomy while standing and third, the difference between viscosity change and volume depletion on aortic augmentation (AIx) and central BP.The burden of this study consists of one visit, with a duration of approximately one hour. The patients will be assigned a group (volume replacement or no volume replacement) depending on the regular receiving care; when a patient experienced negative effects after phlebotomy (such as dizziness, light headedness, weakness and/or collapse), the patient is assigned to receive volume replacement by their attending physician. The techniques used are the Nexfin, the Arteriograph and the MicroScan Video Microscope which will measure central BP, MAP, AIx, stroke volume, heart rate, systemic vascular resistance, forward and backward waves, cardiac output, pulse pressure, baroreflex and objectify microcirculation in supine and standing position with and without counter manoeuvres before and after phlebotomy. Furthermore a short questionnaire will be taken to assess record patients' age, gender, medical history, demographic variables, medication use and co-morbidity. Also length, weight and waist circumference will be measured. Finally a blood sample will be taken before and after the phlebotomy for hemoglobin, plasma viscosity and hematocrit.

Study objective

Recently it has been demonstrated that upon standing wave reflection and central blood pressure (BP) decrease despite an increase in systemic vascular resistance. The decrease in central aortic augmentation and central BP can be attenuated by unilateral leg compression. This suggests that aortic augmentation (AIx) and central BP are sensitive to alterations in venous return. Our principal aim is to assess whether changes in volume status affect aortic augmentation (AIx) and central BP in patients receiving regular phlebotomy while supine and after standing. Because changes in blood viscosity may influence AIx, BP and cardiac output, the current study also aims to assess the difference of BP and AIx in patient who receive volume replacement after.

Study design

A total of six measurement moments are done with the arteriograph: in supine position (t=10), in standing position (t=15) and with countermanouevres (t=20) before the intervention (phlebotomy). After the phlebotomy the same measurement regime is done (t=35, t=40 and t=45, respectively). At the same time a continuous measurement is done with the nexfin (before and after intervention). Objectified parameters are: central BP, AIx, PWV, stroke volume, heart rate, systemic vascular resistance, cardiac output, pulse pressure, baroreflex and MAP. At t=0 and again at t=55 microcirculation is objectified with a SDF-camera. Blood samples (Hb, ht and plasma viscocity) will be collected before (t=25) and after

phlebotomy (t=50).

Intervention

Phlebotomy with or without volume replacement. Each patient serves as his or her own control. The hemodynamic measurements from before the phlebotomy (500ml) are compared to the hemodynamic measurements after phlebotomy.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients aged 18-75 years receiving phlebotomy at regular intervals (for example because of hemochromatosis or polycythemia vera) ;

- Willing to participate ;

- Able to provide informed consent.

Exclusion criteria

- Pacemaker or ICD device ;

- Atrial fibrillation ;

- Mechanical heart valve ;

- Congestive heart failure (≥NYHA III/IV) ;

- Unable to stand up ;

- Uncontrolled hypertension (BP>180/110 mmHg).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	11-06-2013
Enrollment:	42
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-06-2013
Application type:	First submission

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
NTR-new	NL3870
NTR-old	NTR4038
Other	ABR : 44193
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A