Central Hemodynamics, Augmentation index and Microcirculation after Phlebotomy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Red blood cell disorders
Study type	Observational invasive

Summary

ID

NL-OMON38739

Source
ToetsingOnline

Brief title
CHAMP study

Condition

- Red blood cell disorders
- Hepatic and hepatobiliary disorders

Synonym
Heamochroomatosis (Iron overlad), polycythemia (too much red blood cels)

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Augmentation Index, Central blood pressure, Hemodynamics, phlebotomy

Outcome measures

Primary outcome

- Significant difference in aortic augmentation as well as difference in central BP of * 10 mmHg systolic or * 5 mmHg diastolic before and after phlebotomy in supine and standing position with or without counter maneuvers.-

- Difference in aortic augmentation of * 4% as well as difference in central BP of * 10 mmHg systolic or * 5 mmHg diastolic after phlebotomy in patients with or without saline infusion (viscosity changed/unchanged).

Secondary outcome

To assess the effects of phlebotomy on cardiac output and peripheral resistance while supine and after standing

To assess the effects of phlebotomy on forward and backward waves in supine position and after standing

To assess the effects of phlebotomy with saline repletion on cardiac output and peripheral resistance while supine and after standing

To assess the effects of phlebotomy with saline repletion on forward and backward waves in supine position and after standing

Study description

Background summary

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 phlebotomy

Study objective

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 maneuvers (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.

Study design

Experiment with non-invasive measurements of hemodynamics before and after phlebotomy. Each subject serves as his or her own control.

Study burden and risks

We aim to objectify the difference in BP and AIx after phlebotomy to better comprehend in what way phlebobtomy affects BP and central hemodynamics. The burden of this study consists of one visit, with a duration of approximately one hour. 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 maneuvers 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 during and after the phlebotomy for hemoglobin, plasma viscosity and hematocrit.

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

Without volume replacement:
- Patients aged 18-75 years receiving phlebotomy at regular intervals (for example because of hemochromatosis, porphyria and polycythemia vera)
- Known to tolerate phlebotomy
- Willing to participate
- Able to provide informed consent.
Patients which are known to tolerate phlebotomy without any adverse events are included in the *no-volume replacement group.* Patients who have experienced adverse events after phlebotomy in the past, and are previously assigned to receive volume replacement by their attending physician, are included in the *volume replacement group.* We aim to include the same amount of patients in each group.

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: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2013
Enrollment:	42
Type:	Actual

Ethics review

Approved WMO

Date:	05-06-2013
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	NL44193.018.13