The impact of volume loss during blood donation on continuous blood pressure measurements in spontaneously breathing subjects.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34062

Source
ToetsingOnline

Brief title
Volume-BP study

Condition

- Other condition

Synonym
volme loss

Health condition

Vrijwillige bloeddonatie

Research involving

Human

Sponsors and support

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

Intervention

Keyword: hemodynamics, pulse pressure variation, spontaneously breathing, volume loss

Outcome measures

Primary outcome

Changes in the pulse pressure during a respiratory cycle after a 500 ml volume

loss when compared to baseline in spontaneously breathing subjects.

Secondary outcome

Pulse pressure variation (PPV): The percentage change of the pulse pressure

during the breathing/respiratory ventilation cycle.

Continuous systolic blood pressure (SBP)

Continuous diastolic blood pressure (DBP)

Mean arterial pressure (MAP)

Heart rate (HR)

Amount of blood donated in ml (BD)

Demographic volunteer variables: age, sex, race, BMI, comorbidities, current

medication, intoxications.

Study description

Background summary

During a surgical procedure the cardiovascular system will be extended to the

use of anaesthetics, volume therapy, coagulants, blood pressure variations and blood loss. In patients with existing co morbidities this cardiovascular overload may lead to the development of postoperative complications such as pulmonary edema, a temporarily hypertension or cardiac arrhythmias. The department of Anesthesiology of the VUmc recently started to focus on postoperative hemodynamic monitoring in surgical patients who have no arterial entrance and are not ventilated. In order to do so, a continuous blood pressure measurement device (Nexfin) should be validated in order to define its value in this postoperative monitoring of patient hemodynamics. We recently showed that postoperative non-invasive continuous blood pressure measurements during autonomic function testing may be representative for predicting hemodynamic changes using evaluation of the pulse pressure variation (PPV) in spontaneously breathing patients.

Study objective

In this study we aim to validate changes in the pulse pressure after controlled volume loss during blood donation in spontaneously breathing subjects. This validation will contribute to the development of a standardized manner in which the Nexfin device can contribute to the early detection of postoperative complications and to an early threatment of these complications. An adequatly postoperative monitoring will therefore lead to an improvement of the postoperative outcome of patients at risk for the development of mild complications due to anesthesia and surgery.

Study design

This is an open, prospective, observational trial.
The study will be performed in the VU University Medical Center and the blood donation department of Sanquin.
Inclusion of healthy volunteers giving a 500 ml full blood donation.
The study will end when the acquired sample size is reached.
Informed consent will be asked at the Sanquin blood blank before blood donation.
Volunteers are included in the study after signing their informed consent.
In order to perform continuous blood pressure measurements, an arterial blood pressure finger cuff will be placed around the right middle index finger.
The end of the study is marked by the second blood pressure measurement after blood donation.

Study burden and risks

Nexfin device:
Continuous blood pressure measurements will be performed by placing a finger cuff around the middle index of the dominant hand. The hand will be placed in a comfortable position on the abdomen when the patient or volunteer is in a

supine position. Volunteers are asked not to talk or move during testing. This technique is associated with minimal discomfort and no risks for the volunteer.

Supine steady state:
The volunteer will be awake and breath normally while performing the supine steady state for a period of 3 minutes. This is not regarded to induce any discomfort.

Controlled breathing
Volunteers and patients will perform a cycle of metronome-controlled breathing to mimic ventilation conditions. This is regarded to induce minimal discomfort.

Valsalva maneuver:
The VM can be performed by forcibly exhaling against a closed glottis (a closed airway), for instance to detect an inguinal hernia or to clear the ears during diving. In the present study, volunteers and patients will perform a VM by blowing into a manometer-controlled device that allows standardization of the pressure which induces the Valsalva effects. This measurement is associated with minimal discomfort. When necessary, lowering the pressure till 20 mmHg will be tolerated in order to reach a comfortable level.

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

Volunteers giving a blood donation of 500ml full blood.

Exclusion criteria

Body mass index (BMI) 15 < BSA > 35 kg/m2.
Diabetes mellitus.
Underlying cardiovascular diseases.
Use of beta blockers, anti-hypertensive drugs or diuretics.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2011
Enrollment:	47
Type:	Actual

Ethics review

Approved WMO Date:	20-10-2010
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	NL32342.029.10