Dynamic indices of fluid responsiveness and tissue perfusion

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The main objective of this study is to determine the relationship between arterial pressure variability indices and tissue perfusion/oxygenation between normo- and hypovolemia in healthy spontaneously breathing subjects .

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vascular therapeutic procedures
Study type	Observational non invasive

Summary

ID

NL-OMON37776

Source
ToetsingOnline

Brief title
Dynamic indices of fluid responsiveness and tissue perfusion

Condition

- Vascular therapeutic procedures

Synonym
Hypovolemia, low central blood volume

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Arterial pressure variations, Cerebral blood flow, Cerebral/muscle oxygenation, Hypovolemia

Outcome measures

Primary outcome

The primary end-points of this study are cerebral blood flow, cerebral/muscle oxygenation and arterial oxygen saturation. These parameters reflect tissue perfusion/oxygenation.

Secondary outcome

The study parameters which are measured to investigate the influence on the primary end-points are:

- Blood pressure
- Stroke volume
- Heart rate
- Cardiac output
- Tidal volume
- Breathing frequency
- Tilt angle

Study description

Background summary

A too low circulating volume (hypovolemia), and more specifically a too low central blood volume may result in inadequate tissue perfusion with as consequence ischemia and organ failure. In the anaesthesiology and intensive care medicine, intra-venous volume is often administered aiming to improve tissue perfusion and oxygenation. On the other hand, too much circulating

volume (hypervolemia) may evoke pulmonary and interstitial oedema, thereby contributing to further tissue injury with development of organ dysfunction and eventually death. During the last decade, much research concentrated on the development of biomarkers which predict a subject*s volume responsiveness. In mechanically ventilated subjects, arterial pressure variations have shown to be good indices to predict whether a subject will or will not benefit from a fluid challenge (intra-venous volume administration). In spontaneously breathing subjects, a paced breathing frequency of 6 breaths per minute in combination with a respiratory resistor improve the predictive value of arterial pressure variations. The majority of studies limited the investigated end-point on a fluid challenge to cardiac output or stroke volume. However, the ultimate goal of a fluid challenge is an optimisation of tissue perfusion/oxygenation. The present study is designed to investigate the effects of volume expansion (simulated by tilt back) under circumstances of simulated central hypovolemia at the level of the tissues.

Study objective

The main objective of this study is to determine the relationship between arterial pressure variability indices and tissue perfusion/oxygenation between normo- and hypovolemia in healthy spontaneously breathing subjects .

Study design

Observational study.

In the laboratory for Cardiovascular Physiology, hemodynamic parameters (blood pressure (BP), stroke volume (SV), heart rate (HR) and cardiac output (CO)), respiratory parameters (tidal volume, airway pressure/flow) and parameters reflecting tissue perfusion (cerebral blood flow (CBF), cerebral/muscle oxygenation and arterial oxygen saturation) are evaluated under conditions of simulated normovolemia (supine resting position) and hypovolemia (simulated by 30 and 70 degrees head-up tilt positions). The parameters will also be evaluated when the subject is slowly rocking on the tilt table (oscillatory tilting).

Study burden and risks

There are no foreseen risks with participating in this study. The burden for the subject is minimal because all the measurements are non-invasive. The measurements are done using patches placed on the abdomen and chest, a cuff around the finger, breathing through a mouthpiece ans sensors which are attached on the head using a headband and on a forearm muscle. The subject is asked to breath in a breathing pattern of 6 breathes per minute and to breath through a resistor. This can be experienced as uncomfortable, as for headband or mounted fingercuff. However, this does happen for a short time and will

directly disappear at the end of the measurement.

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

Healthy subjects between 18 and 80 years old.

Exclusion criteria

Cardiac arrythmias and absence or insufficient quality of the Doppler and/or NIRS signals.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	28-02-2012
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	NL39582.018.12