Arterial pressure variations during spontaneous breathing

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

Summary

ID

NL-OMON36222

Source
ToetsingOnline

Brief title
Arterial pressure variations during spontaneous breathing

Condition

- Vascular therapeutic procedures

Synonym
hypovolemia, low 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 variation, PPV, respiratory resistor, sponaneous breathing

Outcome measures

Primary outcome

The main study parameter is arterial blood pressure variation.

Secondary outcome

The study parameters which are measured to investigate there influence on the

arterial pressure variations are:

o tidal volume

o airway pressure

o lung compliance

o breathing frequency

o interbeat interval

o thorax impedance

o stroke volume

o tilt angle

Study description

Background summary

In anesthesia and intensive care medicine, intravenous volume is often administered to improve tissue oxygen delivery. Too little circulating volume (hypovolemia) can cause inadequate organ perfusion with ischemia and organ failure. On the other hand, too much circulating volume can cause pulmonary and peripheral edema that contributes to further tissue injury and organ dysfunction. The cardiovascular responses upon volume administration are determined primarily by their effect on the central blood volume. In mechanically ventilated patients, arterial pressure variations have shown to be

good indices to predict if a patient will benefit from intravenous volume administration. However, in spontaneously breathing patients, arterial pressure variations have shown to be less predictive.

Study objective

The main objective is to investigate the effect of tidal volume, airway pressure, breathing frequency, interbeat interval of the heart, respiratory resistance and lung compliance on arterial pressure variation in healthy subjects. The secondary objective is to improve the value of arterial pressure variation as a predictor for fluid responsiveness.

Study design

Observational. In the Laboratory for clinical cardiovascular physiology, blood pressure (BP), Stroke volume (SV), heart rate (HR), cardiac output (CO), tidal volume, airway pressure and flow are evaluated under conditions of simulated normovolemia (supine resting position) and graded hypovolemia (simulated by passive 30 and 70 degrees head-up tilt positions).

Study burden and risks

There is no risk associated with participation in the study. The burden on the subject is minimal because all measurements are non-invasive. The measurements are done using patches placed on the abdomen and chest are attached, a cuff around the finger and breathe through a mouthpiece. Also, the subject is asked to breathe in certain breathing patterns (such as 6 and 10 times per minute) and by using a light resistance to breathing, this can be comfortable. This does happen for a short time and after that the subject can rest and breathe regularly.

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

Healty subjeds between 18 and 80 years old.

Exclusion criteria

arrhytmias

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2011

Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO 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	NL35515.018.11