Time- and frequency domain analysis of cerebrovascular control

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

Summary

ID

NL-OMON38956

Source
ToetsingOnline

Brief title
Cerebrovascular control

Condition

- Heart failures
- Central nervous system vascular disorders
- Vascular hypertensive disorders

Synonym
autonomic control; vessel mechanoregulation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: autoregulation, blood pressure, brain, brain vessels

Outcome measures

Primary outcome

Primary endpoints of this study are comparibility and reproducibility of

quantification of CA with current common methods.

Secondary outcome

- Blood pressure

- Cardiac output

- Cerebrovascular autoregulation capacity

Study description

Background summary

Cerebral autoregulation (CA) as a control mechanism of perfusion pressure takes care of the maintaining of perfusion pressure within the cerebrovascular system and the reflective vasoconstriction of brain vessels for increasing cerebral perfusion pressure (CPP) and vasodilatation when CPP decreases. This change in vessel diameter, to great extent, influences cerebrovascular resistance (CVR). The amount of blood flow towards the brain, the cerebral blood flow (CBF), is inversely related to the CVR. When CA is impaired or absent, CBF will become directly proportionally linked to changes in CPP as was shown by our studies as well as by other authors for diseases as Diabetes Mellitus, the ischemic stroke in large arteries as well as the lacunar brain infarction and sickle cell disease. Diagnostically these diseases do not show differences in performance of CA between individual patients, which complicates the possibility to make a general statement for an entire category. At the moment CA can only be investigated by looking at the response to changes in cardiovascular variables such as blood pressure - usually expressed as mean arterial pressure (MAP) - on CBF.

Cerebral Autoregulation (CA) is the occurrence of vasoconstriction as cerebral

perfusion pressure (CPP) increases and the occurrence of vasodilatation as CPP decreases. This change in vessel diameter, in turn, results in an in- and decrease in Cerebrovascular Resistance (CVR), inversely affecting Cerebral Blood Flow (CBF). When CA is impaired or absent CBF is linearly dependent of CPP. This has proven to be the case in several patient populations, such as: Diabetes Mellitus, Stroke and Sickle Cell disease. Within these populations impairment of CA exists in different gradations complicating retrieving the clinical state the patient resides in. As of now it is impossible to assess CA other than within an experimental laboratory (of physiology). This study hypotheses that more simple methods can be equally useful in the assessment of CA, providing a future outlook for more clinical application of CA assessment.

To measure CA, or more specifically dynamic cerebral autoregulation (dCA) - describing the CVR adaptation over time - , perturbation have to be made to the blood pressure. Eventually this change will be reflected in CBF, which in turn initiates CA: altering CVR. The rate at which CVR changes is a parameter describing dCA.

As subjects' vessel diameter is affected by arterial blood gas concentrations (specifically PaCO2) the perturbations will be executed for three different levels of Partial Pressure of carbon dioxide (PaCO2).

Study objective

At the moment CA can only be assessed in laboratories that have been set-up to perform the specific measurements. This study tries to use a diversity of methods for measuring and analyzing CA and reach a method that is a simplified version of current time- and frequency domain analysis. It is hypothesized that other techniques to assess CA quantification can become available for more clinical patient care and monitoring.

Study design

The experiments consists of resting in supine position followed by position changes (standing up from supine position and from squat position), the execution of thigh cuff maneuvers and the assessment of cerebrovascular reserve capacity with the aid of hypo- and hypercapny.

Study burden and risks

There exist no risks to be expected by taking part to this study. The burden of the subjects is small, because all measurements will be performed non-invasively. In general the physical burden caused by the routine tests in this study are endured well. Within our laboratory it is common practice to continuously monitor patient both through measurement devices and (non-) verbal

communication.

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 and willing and realizing what it means to give informed consent.

Exclusion criteria

Underlying cardiovascular diseases
Diabetes

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):	24-04-2013
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	18-04-2013
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	NL44155.018.13