Early Detection of Central Hypovolemia in Humans

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To detect incipient central hypovolemia preceding symptomatic cerebral hypoperfusion by machine learning models trained on realistic physiological models.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Decreased and nonspecific blood pressure disorders and shock
Study type	Observational non invasive

Summary

ID

NL-OMON40964

Source
ToetsingOnline

Brief title
Detecting central hypovolemia

Condition

- Decreased and nonspecific blood pressure disorders and shock

Synonym
fainting, syncope

Research involving
Human

Sponsors and support

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

Intervention

Keyword: central hypovolemia, cerbral hypoperfusion, machine learning, model

Outcome measures

Primary outcome

Early identification of cerebral hypoperfusion by a machine learning model

based on changes in relevant hemodynamic parameters.

Secondary outcome

not applicable

Study description

Background summary

In healthy subjects cerebral autoregulation maintains cerebral blood flow to prevent the occurrence of hypo- or hyperperfusion of brain tissue. Cerebral autoregulation causes vasoconstriction as cerebral perfusion pressure increases and vasodilatation as cerebral perfusion pressure decreases. However, cerebral autoregulation has its limits, and when the lower limit is reached, cerebral blood flow declines further with development of symptomatic cerebral hypoperfusion. Currently, volume status in anesthetized patients is monitored by heart rate and mean arterial pressure. These parameters are not capable to detect a subclinical hypovolemic state common in the perioperative period. Thus, the application of these parameters to guide fluid therapy may result in unrecognized hypovolemia or hypervolemia and a fundamental problem is that detecting a volume deficit is not straightforward. More meaningful parameters are desired but require monitoring of many signals, which are too complex to interpret for the clinician. Complex software models based on physiological data are needed to be able to evaluate and detect changes in the magnitude of the central blood volume more adequately. A way of doing this is with a machine learning model which takes into account multiple parameters.

Study objective

To detect incipient central hypovolemia preceding symptomatic cerebral hypoperfusion by machine learning models trained on realistic physiological models.

Study design

Subjects are exposed to progressive central hypovolemia (by passive head-up

tilt, lower body negative pressure (LBNP) and active standing. Waveform characteristics of continuous blood pressure, cerebral blood flow velocity and non-invasive applanation arterial carotid and femoral pulse waves are extracted and be used as input in a set of machine learning models to be trained on these data to detect relevant biophysical signals related to cerebral hypoperfusion in multiple timeframes.

Study burden and risks

There are no foreseen risks with participating in this study. The burden for the subject is minimal because all measurements done in this study are non-invasive. The physical load of the routine tests in this study is generally well tolerated. During the entire study, the subject will continuously be monitored to ensure subjects safety.

However, there is always the possbility of reaching syncope and fainting when inducing pre-syncope. This will be carefully monitored and immediately reveresed will this occur.

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 with an age between 18 and 50 years

Exclusion criteria

Subjects known with cardiovascular disease or using medication for cardiovascular disease, hypertension, diabetes or habitual fainting.

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):	11-12-2014
Enrollment:	110
Type:	Actual

Ethics review

Approved WMO

Date:	19-11-2014

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	NL50905.018.14