Prediction of cerebral blood flow and perfusion with arterial pulse wave applied machine learning

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

Summary

ID

NL-OMON54402

Source
ToetsingOnline

Brief title
C-ENTU

Condition

- Other condition

Synonym
Cerebral autoregulation, control mechanisms of brain blood flow

Health condition

Cerebrale autoregulatie onder algehele narcose

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: Edwards Lifesciences

Intervention

Keyword: prediction cbf pulse wave

Outcome measures

Primary outcome

The primary aim of this study is data collection of continuous noninvasive arterial pressure waveform signals with the CS finger cuff, continuous invasive arterial pressure waveform signals when an arterial cannula is already available due to standard of care, continuous noninvasive cerebral oximetry signals, transcranial Doppler ultrasound, capnography and clinical data from patients EMR in surgical patients. These data will be used to predict the likelihood of derangement of physiologic parameters in awake patients before induction of anesthesia and to predict cerebral blood flow using machine learning.

Secondary outcome

Not applicable.

Study description

Background summary

Intra-operative hypotension, even in short periods, is associated with increased mortality, the occurrence of postoperative renal failure, myocardial injury and length of hospital stay. Also the incidence of ischemic stroke is slightly elevated. It is hypothesized that when intra-operative blood pressure declines, cerebral autoregulation (CA), known to keep cerebral blood flow

stable during blood pressure fluctuations, becomes impaired and that brain perfusion becomes jeopardized. Real-time assessment of cerebral autoregulation requires extensive, specialized monitoring and complicated data processing, and is not routinely performed.
Therefore, in daily practice, anesthesiologists strive to maintain mean blood pressure above approximately 60 to 65 mmHg since studies claim that the lower limit of CA is located around this blood pressure level. However, it is becoming increasingly clear that there is a large inter-individual variation in lower limit of CA, and we underestimate the risk of intraoperative cerebral hypoperfusion. In this study we want to collect the beat-to-beat arterial blood pressure curve, cerebral blood flow velocity and cerebral tissue oxygenation to try to predict the cerebral perfusion from the arterial pulse wave.

Study objective

The primary aim of this study is data collection of continuous noninvasive arterial pressure waveform signals with the ClearSight (CS) finger cuff, continuous invasive arterial pressure waveform signals when an arterial cannula is already available due to standard of care, continuous noninvasive cerebral oximetry signals, cerebral flow velocity using transcranial Doppler (TCD) ultrasound and clinical data from patients* electronic medical record (EMR) in surgical patients. These data will serve as a base to attempt to predict cerebral perfusion during surgery using hemodynamic parameters only by use of machine-learning.
The collected digital pressure waveform data will be used to assess the feasibility, the learning and building of an initial ML model using the CS/EV1000/HemoSphere continuous noninvasive arterial pressure signal and internally validate it.

Study design

This is a non-randomized prospective observational data collection study. We will start to monitor beat-to-beat systemic and cerebral hemodynamic parameters (non-invasive finger blood pressure (photoplethysmograph), non-invasive middle cerebral artery blood flow velocity (transcranial Doppler) and non-invasive cerebral tissue oxygenation (Near infra-red spectroscopy) from until at least 30 minutes before the start of surgery until the procedure ends.
We aim to include 100 patients for cardiac and non-cardiac surgery.

Study burden and risks

There are no additional risks or benefits associated with participation. There are no investigational devices used in this study. There are no additional risks associated with the use of the CS/EV1000/HemoSphere monitor other than described in the Instructions for Use. There are also no risks associated with the study procedures. The anesthetic regimes are based on what is currently

used in daily practice and reported in the literature. Patients receive standard anesthesia on basis of daily practice and established pharmacodynamic models that have been shown to be both save and effective.

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

- >=18 years of age
- Informed consent
- Planned for any type of elective surgery/Requiring intubation/Requiring tracheostomy

Exclusion criteria

- Any right-sided structural pathology or reduced function (Tapse <1.5cm)
- Severe cardiac arrhythmias (with high heart rate), including atrial fibrillation
- Abnormal anatomy of the fingers
- Allergy for medication used in study protocol

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-01-2021
Enrollment:	240
Type:	Actual

Ethics review

Approved WMO Date:	18-01-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-04-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	21-04-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL75324.018.20