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

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We hypothesize that the individual lower and upper limits of cerebral autoregulation can be predicted during anaesthesia using machine learning.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28924

Bron
NTR

Verkorte titel
CINTU

Aandoening

Cerebral Autoregulation

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Edwards Lifesciences

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Prediction of cerebral blood flow and autoregulation during anaesthesia using machine

learning

Toelichting onderzoek

Achtergrond van het onderzoek

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.

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 population:

All patients above 18 years of age requiring anesthesia for cardiac and non-cardicac surgery.

Investigation:
Hemodynamic parameters recorded with CS/EV1000/HemoSphere (non-invasive blood pressure monitoring) and invasive blood pressure when an arterial cannula is already available due to standard of care 30 minutes before and during the standard anesthetic regime for at least 30 minutes after start of surgery (for elective surgical patients). Noninvasive cerebral oximetry parameters recorded with the Tissue Oximetry Module of the HemoSphere monitor, and non-invasive cerebral blood flow parameters recorded with transcranial Doppler ultrasound during the above-described period of time.

Main study parameters/endpoints:
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. All data points from these continuous measurements are recorded in real-time and will be used to construct a prediction algorithm, therefore no fixed time points are needed. 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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
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.

Doel van het onderzoek

We hypothesize that the individual lower and upper limits of cerebral autoregulation can be predicted during anaesthesia using machine learning.

Onderzoeksopzet

1

Onderzoeksproduct en/of interventie

6 breaths-per-minute paced breathing

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥18 years of age
- Informed consent
- Planned for any type of elective surgery under anesthesia.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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
- Emergency surgery
- Allergy for medication used in study protocol
- Subjects will be excluded if both noninvasive blood pressure (with the finger cuff) and invasive blood pressure (with an arterial cannula already available due to standard of care) cannot be measured according to the Instructions for Use of the CS/EV1000/HemoSphere system.
- Unability to record transcranial Doppler ultrasound due to anatomical variance (~5% of population)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-01-2021
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9239
Ander register	METC AMC : METC 2020_289

Resultaten