Prediction of Post-induction Hypotension with Arterial Pulse wave applied Machine Learning, a non-randomized prospective data collection observational study.

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Primary 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...

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

Summary

ID

NL-OMON52930

Source
ToetsingOnline

Brief title
PREP trial

Condition

- Other condition

Synonym
hypotension, low blood pressure

Health condition

Hemodynamiek, intra-operatief

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Anesthesiology, Hypotension, Machine learning, Post induction

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 and clinical data from patients EMR in surgical and ICU 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 the occurrence of post-induction hypotension and IOH using 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.

The collected data will be used to assess whether the non-invasive arterial pressure waveform measured at the finger level using the CS/EV1000/HemoSphere system or the invasive arterial pressure waveform measured with an arterial

cannula exhibits any distinctive morphological characteristics in awake patients having post-induction hypotension, defined as MAP < 65 mmHg for at least 1 minute, in the first 20 minutes after induction, or early IOH, defined as MAP < 65 mmHg for at least 1 minute in the first 30 minutes after start of surgery. The morphologic characteristics include parameters derived from arterial wave signals, such as baroreflex sensitivity, stroke volume, elastance and dP/dt.

Secondary outcome

Secondary aim is the correlation between severity of post-induction hypotension, waveform and cerebral oximetry data, patient history characteristics and the incidence and severity of hypotension during the surgical procedure or the intubation or elective tracheostomy in the ICU.

Study description

Background summary

Hypotension during surgery is associated with increased morbidity and mortality. The majority of patients will have post-induction hypotension (PIH), a mean arterial blood pressure below 65 mmHg for at least one minute and occurring during the first 20 min after anesthesia induction. PIH is highly prevalent and probably occurs more often than intraoperative hypotension (IOH). Early IOH is described as a mean arterial blood pressure below 65 mmHg for at least one minute occurring in the first 30 minutes after the start of surgery. Also, PIH is very common in Intensive Care Unit patients and is likely to have an equally negative effect on outcome as any other type of IOH. Even short periods of hypotension are known to contribute to the occurrence of postoperative renal failure, myocardial injury, stroke and length of hospital stay.

The early identification and treatment of hypotension is clinically relevant. Current therapies are reactive and are started after hypotension occurs. Post-induction hypotension (PIH) is likely to occur in the majority of cases in

the face of boluses of anesthetic agents causing severe vasodilation and even temporary cardiac depression as a surgical stimulus is missing. Since any type of hypotension is likely to have negative effects, prevention is warranted. A machine-learning algorithm based on the arterial pressure signal for the prediction of post-induction hypotension, in analogy of the recently FDA-approved intra-operative Hypotension Prediction Index (HPI), would eventually allow preemptive treatment and prevention of post-induction hypotension altogether.

Study objective

Primary 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 and clinical data from patients* electronic medical record (EMR) in surgical and ICU 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 the occurrence of post-induction hypotension and IOH using machine learning.

The collected digital pressure waveform will be used to assess the feasibility, the learning and building of an initial machine learning model using the CS/EV1000/HemoSphere continuous (non)invasive arterial pressure signal and internally validate it.

Secondary Objectives:
To correlate pre-induction waveform and patient history characteristics, alterations in cerebral oximetry, used medication during induction and maintenance of anesthesia, and the occurrence of events (acute kidney injury, myocardial injury, stroke, in-hospital length of stay and 30-day mortality) during the first 30 days after induction of anesthesia, to PIH and IOH.

Study design

This is a non-randomized prospective observational data collection study that will take place only in the Amsterdam UMC, location AMC in the Netherlands. We estimate that inclusion will take 18 to 45 months from initiation of study (aim December 2018; actual start of the trial: 7th of January 2019).

Electronic data collection of continuous (non)invasive arterial pressure waveform signals and cerebral oximetry signals takes places with the CS/EV1000/HemoSphere system in awake patients before induction of anesthesia. In addition to noninvasive and invasive arterial pressure waveform data and noninvasive cerebral oximetry data, the data collection will require

deidentified patient medical records/anesthesia charts.
We evaluate hemodynamic parameters at least 30 minutes before to a minimum of 20 minutes after induction and its correlation with post-induction hypotension for ICU patients requiring intubation or elective tracheostomy.
We evaluate hemodynamic parameters at least 30 minutes before induction to a minimum of 30 minutes after start of surgery and its correlation with PIH or IOH for elective surgical patients.

We aim to include at least 600 and maximally 1100 patients for elective surgery or for intubation or elective tracheostomy in the ICU.

Phase 1A:
A pilot phase comprising 100 elective surgical patients. Standard of care is performed and timing and dosing is left to the judgement of the attending anesthesiologist.

Phase 1B:
Continuation of phase 1A, with the additional inclusion of ICU patients requiring intubation or elective tracheostomy. Invasive blood pressure data will be collected when an arterial cannula is already available due to standard of care and noninvasive measurements of blood pressure and cerebral oximetry in both surgical and ICU patient groups. Standard of care is performed and timing and dosing of anesthetics is left to the judgement of the attending anesthesiologist or intensivist.

After phase 1 we will perform an interim analysis to determine the number of patients needed in phase 2.

Phase 2:
A non-randomized prospective observational data collection study in at least 600 and maximally 1100 (dependent on the interim analysis) elective surgical patients or ICU patients requiring intubation or elective tracheostomy. An amendment will be submitted if there are changes to the protocol.

Phase 3:
Data collection in 100 additional patients to perform an external validation of the predictive algorithm.

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. We give 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

Elective surgical patients:
- >=18 years of age
- Informed consent
- Planned for any type of elective surgery

Intensive Care Unit patients requiring intubation:
- >= 18 years of age
- Informed consent or deferred consent
- Requiring (emergency) intubation

Intensive Care Unit patients requiring elective tracheostomy:
- >= 18 years of age
- Informed consent or deferred consent
- Requiring elective tracheostomy

Exclusion criteria

Elective surgical patients:
- Any right-sided structural pathology or reduced cardiac function (Tapse <1.5cm) (only phase 2)
- Severe cardiac arrhythmias (with high heart rate), including atrial fibrillation
- Abnormal anatomy of the fingers
- Emergency surgery (only phase 2)
- 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.

Intensive Care Unit patients requiring intubation:
- 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.

Intensive Care Unit patients requiring elective tracheostomy:
- 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.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-01-2019
Enrollment:	1300
Type:	Actual

Ethics review

Approved WMO Date:	13-12-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	19-07-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	17-10-2024
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214

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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	NL67484.018.18
Other	NL7810