Predicting Post-Induction Hypotension

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Post-induction (and intra-operative) hypotension is a frequent finding in patients scheduled for surgery or intubation/tracheostomy in the ICU, and with the development of a machine learning model, we will be able to predict hypotensvie episodes...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29121

Bron
Nationaal Trial Register

Verkorte titel
PREP-trial: Prediction of Post-Induction Hypotension

Aandoening

Post-induction hypotension, intra-operative hypotension, acute kidney injury, stroke, myocardial injury, mortality.

Ondersteuning

Primaire sponsor: Edwards Lifesciences
Overige ondersteuning: Edwards Lifesciences

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Collection of continuous noninvasive arterial pressure waveform signals with the ClearSight and clinical data to 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 using machine learning.

Toelichting onderzoek

Achtergrond van het onderzoek

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.
PIH is very likely to have an equally negative effect on outcome as any other type of intra-operative hypotension. 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 PIH, in analogy of the recently FDA-approved intra-operative Hypotension Prediction Index, would eventually allow preemptive treatment and prevention of post-induction hypotension altogether.

The primary aim of this study is data collection of continuous noninvasive arterial pressure waveform signals with the ClearSight finger cuff and clinical data from patients' electronic medical record in surgical patients and Intensive Care Unit patients who need intubation or elective tracheostomy, to 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 intra-operative hypotension using machine learning.

Doel van het onderzoek

Post-induction (and intra-operative) hypotension is a frequent finding in patients scheduled for surgery or intubation/tracheostomy in the ICU, and with the development of a machine learning model, we will be able to predict hypotensvie episodes following administration of anesthetic agents.

Onderzoeksopzet

Patients will be connected to the ClearSight system 30 minutes prior to start of induction of anesthesia. Data will be continuously collected until at least 30 minutes after start of surgery, or until 20 minutes after start induction (for ICU patients).

Onderzoeksproduct en/of interventie

Not applicable.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years or older
- Planned for any type of elective surgery or for intubation/tracheostomy in the ICU

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
- Noninvasive blood pressure (with the finger cuff) or invasive blood pressure (with an arterial cannula) can not be measured

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
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:	07-01-2019
Aantal proefpersonen:	1100
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	18-06-2019
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	NL7810
Ander register	METC AMC : METC 2018_271, NL67484.018.18

Resultaten