The HYPE-2 Randomized Clinical Trial

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We hypothesize that the use of this algorithm will reduce hypotension as measured by the time weighted average (TWA) during both the off-pump phase of on-pump coronary artery bypass graft (CABG) surgery and the mechanically ventilated phase of post-...

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

Samenvatting

ID

NL-OMON22510

Bron
NTR

Verkorte titel
HYPE-2

Aandoening

All adult patients undergoing elective on-pump CABG surgery or CABG with additional single heart valve surgery (e.g. valve repair or replacement), requiring a radial arterial line and an intended target MAP of 65 mmHg or above during both surgery (excluding cardiopulmonary bypass pump time (CBP)) and during mechanically ventilated phase of duration of ICU admission.

Ondersteuning

Primaire sponsor: Amsterdam UMC
Overige ondersteuning: Edwards Lifesciences, Irvine California, USA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The overall time-weighted average (TWA) of hypotension during both the off-pump phases of on-pump CABG surgery and the mechanically ventilated phase of post-operative ICU admission (or 8 hours maximum)

Toelichting onderzoek

Achtergrond van het onderzoek

Hypotension during cardiac surgery and post-operative intensive care unit (ICU) admission is associated with adverse outcomes. Current management of hypotensive episodes is predominantly reactive and rather occurs with delay. Edwards Lifesciences (Irvine, CA) has developed an algorithm using continuous invasively-measured arterial waveforms to predict hypotension with high accuracy minutes before blood pressure actually decreases, the so called Hypotension Prediction Index (HPI). HPI has never been tested in cardiac surgery patients or patients admitted to the ICU. Elective coronary artery bypass graft (CABG) patients will be randomized in two groups, treatment and conventional. Treatment group: in addition to standard monitoring (continuous arterial blood pressure monitoring and pulse pressure variation), patients are connected to a HemoSphere monitor which provides additional advanced hemodynamic variables (e.g. cardiac output, systemic vascular resistance) and the HPI. The treating anesthesiologist, anesthesia nurse, intensivist and critical care nurse are trained to use these variables and are provided with a diagnostic flowchart to determine the cause (preload, contractility and afterload) of the upcoming hypotensive (mean arterial pressure (MAP) < 65 mmHg) event. Timing of treatment and choice of treatment is then left to the discretion of the attending anesthesiologist, anesthesia nurse, intensivist and critical care nurse. Conventional arm: institutional standard of care with an intention to keep MAP equal to or above (≥) 65 mmHg. The HemoSphere will be connected for data extraction but fully covered and silenced.

Doel van het onderzoek

We hypothesize that the use of this algorithm will reduce hypotension as measured by the time weighted average (TWA) during both the off-pump phase of on-pump coronary artery bypass graft (CABG) surgery and the mechanically ventilated phase of post-operative ICU admission.

Onderzoeksopzet

1. Pre-surgery: blood samples
2. During surgery and mechanically ventilated duration of ICU stay: blood samples and connecting arterial line to HemoSphere monitor
3. Post-ventilated ICU phase: blood samples and connecting arterial line to HemoSphere monitor (for 8 hours maximum)

Onderzoeksproduct en/of interventie

Treatment group: in addition to standard monitoring (continuous arterial blood pressure monitoring and pulse pressure variation), patients are connected to a HemoSphere monitor which provides additional advanced hemodynamic variables (e.g. cardiac output, systemic vascular resistance) and the HPI. The treating anesthesiologist, anesthesia nurse, intensivist and critical care nurse are trained to use these variables and are provided with a diagnostic flowchart to determine the cause (preload, contractility and afterload) of the upcoming hypotensive (mean arterial pressure (MAP) < 65 mmHg) event. Timing of treatment and choice of treatment is then left to the discretion of the attending anesthesiologist, anesthesia nurse, intensivist and critical care nurse.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Aged 18 years or older at inclusion
• Planned for elective on-pump CABG surgery or CABG with additional single heart valve surgery (e.g. valve repair or replacement)
• Planned to receive standard monitoring for cardiac surgery
• Target MAP of 65 mmHg or above during surgery
• Target MAP of 65 mmHg or above during the mechanically ventilated phase of ICU admission

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Known cardiac shunts (significant)
• Severe cardiac arrhythmias (including but not limited to persistent atrial fibrillation prior to surgery)
• Expected to receive an hemodynamic assist device (e.g. intra-aortic balloon pump) during surgery
• Dialysis dependent kidney failure prior to surgery
• Planned to receive Perioperative Goal Directed Therapy (PGDT) other than standard intraoperative care
• Previous cardiac surgery in medical history

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-05-2021
Aantal proefpersonen:	130
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	30-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 51117
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9449
CCMO	NL76236.018.21
OMON	NL-OMON51117

Resultaten