The HYPE-2 Randomized Clinical Trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22510

Source
NTR

Brief title
HYPE-2

Health condition

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.

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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)

Secondary outcome

All secondary objectives will be analyzed for the overall duration of both the off-pump phases of on-pump CABG surgery and the mechanically ventilated phase of post-operative ICU admission (or 8 hours maximum):
• Incidence of hypotension
• Time spent in hypotension
• The percentage of time in hypotension
• The AUC of a MAP < 65 mmHg
*The above-mentioned parameters including TWA will also be assessed for hypertension (MAP > 100 mmHg) and for the HPI alarms (HPI > 75).

• Treatment choice (i.e., vasopressors, blood transfusions, fluids, inotropes, position changes, decrease in anesthetics)
• Treatment dose
• Time to treatment. If an alarm or hypotensive event had more than 1 treatment, the time to first treatment will be used.
• Number of treatments

Exploratory outcomes:
• Does HPI with diagnostic guidance affect the severity of-, incidence of- and/or time spent in hypertension during:
o the pre- and post-pump phases of on-pump CABG surgery
o the mechanically ventilated phase of post-operative ICU admission (or 8 hours maximum)
• Does HPI with diagnostic guidance affect the severity of-, incidence of- and/or time spent in HPI alarm during:
o the pre- and post-pump phases of on-pump CABG surgery?
o the mechanically ventilated phase of post-operative ICU admission (or 8 hours maximum)?
• To study the compliance of anesthesiologists, anesthesia nurses, intensivists and critical care nurses to the diagnostic guidance protocol and nurse driven hypotension protocol (ICU only) (assessed by number of- and reason for protocol deviations).
• To study whether a decrease in TWA of hypotension is associated with a change in biomarkers for organ damage (including but not limited to: creatinine, lactate, creatinine kinase MB, hematocrit, central venous oxygen saturation and brain natriuretic peptide)
• To study the relation between transesophageal echocardiogram (TEE) observations and hemodynamic parameters derived from continuous arterial waveforms (using the HemoSphere monitor) during hemodynamic instability
• To study whether reducing the severity of hypotension with HPI and diagnostic guidance during both the surgery and the first hours of ICU admission results in a sustained effect on the severity of-, incidence of- and time spent in hypotension, after HPI and diagnostic guidance are disconnected.
• To study control group’s treatment behavior after silent alarms to which they were blinded and compare this with treatment behavior after alarms in the intervention group

Study description

Background summary

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.

Study objective

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.

Study design

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)

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-05-2021
Enrollment:	130
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	30-04-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 51117

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results