Mean arterial pressure alarm compared to hypotension prediction index in preventing intraoperative hypotension

Published: 20-09-2023 Last updated: 30-01-2025

Primary Objective: The performance in preventing intraoperative hypotension of a MAP treatment alarm of 72 mmHg compared to the performance of the HPI alarm. Secondary Objectives: - The correlation between the MAP signal and HPI signal - The...

| Ethical review | Approved WMO |
|-----------------------|-----------------|
| Status | Pending |
| Health condition type | Other condition |
| Study type | Interventional |

Summary

ID

NL-OMON53215

Source ToetsingOnline

Brief title MARTINI

Condition

• Other condition

Synonym Intraoperative hypotension, Low blood pressure

Health condition

Intra-operative Hypotension

Research involving

Human

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Sponsors and support

Primary sponsor: Medisch Spectrum Twente Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: HPI, Hypotension Prediction Index, Intraoperative hypotension, Mean arterial pressure

Outcome measures

Primary outcome

The primary outcome measure is the area under the threshold (AUT) of

hypotension (defined as MAP<65 mmHg for at least one minute) during surgery.

Secondary outcome

- Incidence of hypotension
- Time spend in hypotension
- Length of hypotensive episodes
- Time weighted average of hypotension
- Cross-correlation between MAP values and HPI values
- Troponin level before and after surgery
- Creatine level before and after surgery
- 30-day mortality after surgery

Study description

Background summary

Intraoperative hypotension (IOH) is common in surgical patients and gives an increased risk for 30-day mortality, acute kidney injury and myocardial injury. A method to predict hypotension could help anaesthesiologists to treat in a proactive, instead of a reactive way, to ultimately prevent hypotension. Hatib et al. developed an algorithm to predict hypotension 15 minutes before the blood pressure drops: the Hypotension Prediction Index (HPI). However, it is suggested that the positive effect of the HPI could also be due to the increased clinician awareness and it is found that there is a high correlation between the HPI signal and the MAP signal. It is hypothesised that the positive effect of the HPI could also be achieved with a mean arterial (MAP) treatment threshold of for example 72 mmHg. In this research the performance in preventing IOH triggered by a MAP based alarm is compared to the performance of the HPI. It is hypothesised that their predictive performance would be comparable.

Study objective

Primary Objective:

The performance in preventing intraoperative hypotension of a MAP treatment alarm of 72 mmHg compared to the performance of the HPI alarm.

Secondary Objectives:

- The correlation between the MAP signal and HPI signal
- The incidence and severity of intraoperative hypotension

- The incidence of acute kidney injury, myocardial injury and 30-day mortality after surgery

Study design

This is a monocentre randomized controlled trial (RCT). This RCT consists of two arms which are explained below:

1. HPI treatment alarm: The HemoSphere advanced monitor with HPI software will be connected to the arterial line of the patient. The anaesthesiologist and anaesthesia nurse are provided with an alarm when the HPI value exceeds 85.

2. MAP treatment alarm of 72 mmHg: The HemoSphere advanced monitor with HPI software will be connected to the arterial line of the patient. The anaesthesiologist and anaesthesia nurse are provided with an alarm when the MAP value drops below 72 mmHg.

Intervention

The HemoSphere Advanced Monitor with hypotension prediction index (HPI) software is the investigated product in this research. With the help of the HPI algorithm, hypotension can be predicted up to 15 minutes before the blood

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pressure drops. When the chance of a hypotensive event in the future increases, the value for HPI increases ranging from 0 to 100.

Study burden and risks

The HemoSphere advanced monitor with HPI software will be connected to the arterial line, this provides no extra risks for the participants. The monitor has a CE-mark and will be used within the intended use and is already part of standard care in our hospital. The anaesthesiologists and nurse anaesthetist are free to decide themself whether treatment will be initiated and which treatment is most appropriate.

Contacts

Public Medisch Spectrum Twente

Koningsplein 1 Enschede 7512 KZ NL **Scientific** Medisch Spectrum Twente

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Inclusion criteria

- Informed consent

- Aged 18 years or older

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- Planned for moderate- or high-risk elective non-cardiac surgery under general anaesthesia

- Need for continues blood pressure monitoring with the help of an arterial line during surgery

- Target MAP of 65 mmHg during surgery
- Elective surgery

Exclusion criteria

- Target MAP higher or lower than 65 mmHg
- Current persistent cardiac arrhythmias, including atrial fibrillation
- Liver and vascular surgery with vascular clamping
- Hypotension before surgery, defined as MAP<65mmHg
- Patients requiring dialysis
- Severe aortic valve stenosis
- Known clinically important cardiac shunts
- Congestive heart failure

Study design

Design

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

Recruitment

| NL | |
|---------------------------|-------------|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-08-2023 |
| Enrollment: | 0 |
| Туре: | Anticipated |

Medical products/devices used

| Generic name: | HemoSphere Advanced Monitor with HPI algorithm |
|---------------|--|
| Registration: | Yes - CE intended use |

Ethics review

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| Approved WMO | |
|--------------------|---|
| Date: | 20-09-2023 |
| Application type: | First submission |
| Review commission: | MEC-U: Medical Research Ethics Committees United (Nieuwegein) |

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 CCMO ID NL84210.100.23