MitoPO2 guided resuscitation to prevent shock during cardiac surgery

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To compare the use of mitoPO2 with the use of conventional markers in guiding interventions to treat shock in patients undergoing cardiac surgery

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

Summary

ID

NL-OMON57062

Source
ToetsingOnline

Brief title
Targeting MitoPO2 during cardiac surgery

Condition

- Other condition
- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
circulation, Shock

Health condition

Shock

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: De Nederlandse Hartstichting

Intervention

Keyword: Cardiac surgery, MitoPO2, Organ failure

Outcome measures

Primary outcome

Incidence of AKI in the first 48 hours after cardiac surgery.

Secondary outcome

nvt

Study description

Background summary

In the Netherlands, 14,500 patients undergo cardiac surgery annually. Approximately 36% of all patients undergoing cardiac surgery develop multiple-organ failure, in particular acute kidney injury (AKI). This lengthens hospital stay and significantly hinders recovery. Central in the aetiology of organ failure is circulatory shock, where organs do not receive an adequate supply of oxygen rich blood, leading to organ failure. Shock is challenging to treat peri-operatively as there is no marker which measures the oxygen supply to tissue directly. As a result, patients are often under or over-resuscitated, both associated with organ failure and death. Currently, indirect and markers are used to guide treatment of shock, however
these markers are unspecific. Disturbances in the microcirculation create a dissociation between these indirect markers and the true tissue oxygenation inside organs. These limitations highlight the need for the direct measurement of tissue oxygenation. The recent development of the protoporphyrin-IX delayed lifetime technique allows non-invasive bedside measurement of the mitochondrial oxygen tension in the cell (mitoPO2). The mitochondria are the most downstream of oxygen supply and demand balance and its value is therefore applicable regardless of the status of other macro- and microcirculatory variables. We have recently shown that a low mitoPO2 is a highly accurate early independent predictor of the occurrence of AKI after cardiac surgery. As such, mitoPO2 could be the ideal marker for personalized resuscitation, particularly

benefitting female patients. The hypothesis is that the use of mitoPO2 to guide shock treatment will reduce the incidence of organ failure after cardiac surgery as compared to the use of conventional monitoring. In a randomized clinical trial in 160 cardiac surgery patients, a mitoPO2-based algorithm to guide administration of fluids and vaso-active agents will be compared to monitoring using conventional parameters for the incidence of AKI , cardiac injury and functional outcome.

Study objective

To compare the use of mitoPO2 with the use of conventional markers in guiding interventions to treat shock in patients undergoing cardiac surgery

Study design

single center open label randomized controlled superiority trial

Intervention

Use of mitoPO2 to guide therapy for shock during and 24 hours after cardiac surgery in the intervention group compared to use of standard monitoring to guide therapy in the control group

Study burden and risks

The subjects receive usual care and do not require deviation from standard protocol, regardless of their allocation. The COMET*s intraoperative non-invasive measurements are regarded as safe and do not result in any increased risk. Administration of a 5-aminolevulinic acid patch to the shoulder that is necessary for the mitoPO2 measurement causes slight local erythema, but no other reactions. Non-invasive measurements of mitoPO2 intra operatively and post operatively use a sensor placed on the skin. Blood samples for monitoring and kidney biomarkers are taken from an existing arterial catheter amounting to 12ml of blood drawn per patient. Treatment decisions follow algorithms according to the discretion of medical specialists and in line with current guidelines. Possible benefits in the intervention group include a reduced incidence of organ dysfunction and acute kidney injury in the investigational arm.

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

High risk patients undergoing elective cardiac surgery

Exclusion criteria

- Brown plaster allergy
- Mitochondrial disease
- Off-pump CABG
- Heart transplantation
- Emergency surgery
- Participation in a fast track recovery after surgery
- Insufficient signal quality of mitoPO2 at baseline
- Mechanical assist device (ECMO, IABP, Impella)

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):	01-12-2024
Enrollment:	122
Type:	Anticipated

Medical products/devices used

Generic name:	COMET with ALAcare plaster
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	31-10-2024
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL85974.078.24