Is a dropping mitoPO2 suggestive for the development of acute kidney injury and/or postoperative cognitive dysfunction after cardiac surgery?

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Primary Objective: the relation between the occurrence of CSA-AKI and the duration of peri-operative low mitoPO2 measurements (

Ethical review	Approved WMO
Status	Completed
Health condition type	Deliria (incl confusion)
Study type	Observational non invasive

Summary

ID

NL-OMON50959

Source
ToetsingOnline

Brief title
MitoPO2 for postoperative CSA-AKI and POCD

Condition

- Deliria (incl confusion)
- Renal disorders (excl nephropathies)

Synonym
Cardiac Surgery Associated Acute Kidney Injury, kidney damage

Research involving
Human

Sponsors and support

Primary sponsor: Anesthesiologie

Source(s) of monetary or material Support: Photonics Healthcare BV

Intervention

Keyword: Acute Kidney Injury, Coronary artery bypass grafting, Mitochondria, Oxygen

Outcome measures

Primary outcome

- MitoPO2 (mmHg) measured semi-continuously peri-operatively and during 48 hours post-operatively using the automated setting of the COMET-device.

- Serum creatinine and 24-hour urine output, measured daily to monitor the onset of CSA-AKI .

Secondary outcome

- CSA-AKI biomarkers, TIMP-2 and IGFBP-7, within 48 hours after ICU admission. These will be obtained during standard care sampling moments

- Pre-operative baseline psychometric testing, using the MOCA, RVLT, TMT A en B, Grooved Pegboard Test, Hospital Anxiety and Depression Scale (HADS)

- Post-operative psychometric testing, performed one week after cardiac surgery using the RVLT, TMT A and B, Grooved Pegboard Test and HADS

- Post-operative psychometric testing performed three months after cardiac surgery using the RVLT, TMT A and B, Grooved Pegboard Test and HADS

- Standard hemodynamic parameters and biomarkers are measured throughout the operation and the first 48 hours on the ICU:
Blood pressure (mmHg), Peripheral perfusion index, Heart rate (bpm), Oxygen saturation (%), Core body temperature (degrees Celsius), End tidal carbon dioxide (kPa),Pump flow rate (L/min), Oxygen concentration of the fresh gas flow to the oxygenator of the pump (%), Haemoglobin (g/dl) and haematocrit (%)

Oxygen delivery (DO2, ml/min) Temperature (degrees Celsius), Delta temperature

(degrees Celsius), Capillary refill in seconds,

Urine production and fluid balance (ml/24 hours),

-The length of ICU stay (days), length of hospital stay (days)

-Routine laboratory values (haemoglobin g/dl, serum creatinine (µmol/l), etc.),

-The occurrence of delirium

-Adverse events

Study description

Background summary

Cardiac-surgery-associated acute kidney injury (CSA-AKI) is a common complication after cardiac surgery. CSA-AKI is independently associated with increased morbidity and mortality. Central in the development of CSA-AKI is the imbalance between oxygen supply and demand. This is often not recognized in time and can therefore not be prevented. Previous studies have shown the potential of monitoring cutaneous mitochondrial oxygen tension (mitoPO2) by the recently introduced Cellular Oxygen METabolism (COMET) (Photonics Healthcare B.V., Utrecht).This study will investigate whether there is a correlation between perioperative duration of low mitochondrial oxygen tension (<20 mmHg) and CSA-AKI. Since post-operative cognitive dysfunction (POCD) after cardiac surgery may also be caused by an oxygen deficiency in the tissue, we will further investigate the relationship between between perioperative duration of low mitochondrial oxygen tension (<20 mmHg) and POCD.

Study objective

Primary Objective: the relation between the occurrence of CSA-AKI and the duration of peri-operative low mitoPO2 measurements (<20 mmHg).
Secondary Objective:
- To study the relationship between the occurrence of postoperative cognitive dysfunction (POCD) and the duration of low mitoPO2 (<20 mmHg) during and up to 48 hours after cardiac surgery.
- To study the relationship between the duration of low mitoPO2 (<20 mmHg) during and up to 48 hours after cardiac surgery and the post-operative measured cardiac surgery associated acute kidney injury (CSA-AKI) biomarkers: TIMP-2 and IGFBP-7

- To study the relationship between mitoPO2 and the standard hemodynamic monitoring parameters and other biomarkers measured during coronary artery bypass grafting (CABG)
- To study the relationship between low mitoPO2 (<20 mmHg) during and up to 48 hours after cardiac surgery and the occurrence of delirium.
- To study the relationship between low mitoPO2 (<20 mmHg) during and up to 48 hours after cardiac surgery and the stay length in the intensive care unit (ICU), and the stay length in the hospital.
- To monitor adverse events related to prolonged usage of the aminolevulinic acid plasters.

Study design

Single center observational study

Study burden and risks

There are no direct benefits for the subjects enrolled in the study.

ALA is clinically used in photodynamic diagnosis and therapy of cancer. Administration of ALA is safe, but transient local photosensitisation requires participants to limit exposure to (sun)light 24 hours after the treatment. This can easily be achieved by covering the site where the ALA plaster has been placed with a light shielding plaster.

The PpIX-TSLT technique likely to be safe, proven by research on healthy volunteers. Since the research with healthy volunteers it has safely been used in neurosurgical patients (MEC-2015-342) , cardiothoracic surgery requiring cardiopulmonary bypass (MEC-2017-532), in large abdominal surgery patients (MEC 2017-556) and in patients admitted to the Intensive Care Unit.(22, 26). The possible effect of phototoxicity after PpIX induction is always potential risk, but because the PpIX-TSLT uses short-pulsed excitation and total light dosage less than used in photodynamic therapy, this risk is considered to be very low (8, 27).

The COMET Sensor Holder has not been used in clinical trials before. It has to be attached the arm of the patient peri- and post-operatively, which gives some restrictions in freedom of movement. Since the patients are bedridden the first days after CABG, we do expect this will cause extra burden on the patients. The COMET Sensor Holder can potentially cause bruising or pressure ulcers from pressure during surgery. Measures such as relieving pressure points with cotton wool will be taken in order to prevent this.

The biomarkers are collected during standard care sampling, so this will be now extra burden to the patient.

The psychometric tests will cost the patients time, about an hour per for all tests, so in total three hours extra. The baseline measurements and the measurements after one week are expected to be performed in the hospital. For the psychometric testing after three months, a dedicated team will visit the subject at home to keep the burden for the patients as low as possible. Since the tests do not contain sensitive questions and the included patients and tests can either be performed during their admission to the hospital or in their own home at their own time, it is deemed as a small burden for the patients.

Overall, the risks are considered negligible and the burden small.

Contacts

Public
Selecteer

Doctor Molewaterplein 40
Rotterdam 3015GD
NL
Scientific
Selecteer

Doctor Molewaterplein 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Age over 18 years
- Acceptable proficiency of the Dutch language
- Scheduled for Coronary Artery Bypass Grafting requiring cardiopulmonary bypass and who have a high risk of developing AKI, according to the AKICS prediction score

Exclusion criteria

- Presence of mitochondrial disease
- Pregnancy/lactation
- Patients with skin lesions on upper arm/shoulder which impede measurements
- Porphyria
- Known intolerance to components of the ALA plaster
- Patients uncapable of providing informed consent, due to a mental condition interfering with the ability to understand the provided information

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-08-2021
Enrollment:	83
Type:	Actual

Medical products/devices used

Generic name:	COMET
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-02-2021
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

ID: 28295
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL75770.078.20