MitoPO2 for postoperative CSA-AKI and Delirium

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Primary Objective: the relation between the occurrence of CSA-AKI and the duration of peri-operative low mitoPO2 measurements (<20 mmHg). Secondary Objective: The relation between the occurrence of delirium and the duration of...

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational non invasive

Summary

ID

NL-OMON28295

Source
Nationaal Trial Register

Brief title
MitoPO2 for postoperative CSA-AKI and Delirium

Condition

- Renal disorders (excl nephropathies)

Health condition

Coronary artery bypass (CABG) requiring cardiopulmonary bypass and who have a high risk of developing CSA-AKI, according to the AKICS prediction score

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: sponsor

Intervention

- Medical device

Explanation

Outcome measures

Primary outcome

To study the relationship between the occurrence of acute kidney injury (AKI) and the duration of low mitoPO2 (<20 mmHg) during and up to 48 hours after cardiac surgery.

Secondary outcome

"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"

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 delirium after cardiac surgery may also be caused by an oxygen deficiency in the tissue, we will further investigate the relationship between perioperative duration of low mitochondrial oxygen tension (<20 mmHg) and delirium.

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: The relation between the occurrence of delirium and the duration of perioperative low mitoPO2 measurements (<20 mmHg).

Study design

Single center observational study

Contacts

Public
Erasmus Medical Center Rotterdam
Calvin de Wijs

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Scientific
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Calvin de Wijs

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Eligibility criteria

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

Inclusion criteria

- Age over 18 years - Acceptable proficiency of the Dutch language - Scheduled for Coronary Artery Bypass Grafting (CABG) surgery requiring cardiopulmonary bypass and who have a high risk of developing CSA-AKI, according to the AKICS prediction score (16)

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 phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2021
Enrollment:	80
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

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

ID: 50959
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9669
CCMO	NL75770.078.20
OMON	NL-OMON50959

Study results