

Use of intraoperative cerebral and renal region Near infrared spectroscopy to predict postoperative outcome; a prospective observational study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23984

Source

Nationaal Trial Register

Brief title

TBA

Health condition

Non-cyanotic, left to right shunt congenital heart disease

Sponsors and support

Primary sponsor: UMCG

Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

The aim of this study is to determine if cerebral NIRS values and renal region NIRS values are

predictors for postoperative AKI in infants with non-cyanotic, left to right shunt congenital heart disease.

Secondary outcome

We would like to determine if cerebral NIRS and regional region NIRS are correlated, which lets us determine if we only need to use 1 sensor spot placement in the future.

We would also like to determine which deviation from baseline NIRS values give the clinician the information to redirect intra-operative care.

Study description

Background summary

Background: Postoperative acute kidney injury (AKI) is a frequent complication after cardiac surgery in pediatric patients, ranging from 20 to 86% depending on the population and used definition of AKI. The diagnosis of renal injury is commonly based on creatinine elevation, but this biomarker only increases when an extensive kidney injury has already developed.

Literature advises using the KDIGO criteria (combination of serum creatinine values and urine output) to assess the degree of AKI. Since renal hypoperfusion and hypoxia are among the most important insults contributing to postoperative AKI, near-infrared spectroscopy (NIRS), measuring regional tissue saturation (StO₂) might prove useful in the real-time detection of renal tissue hypoxia, alerting the clinician to redirect care to prevent a potential ischemic insult and kidney injury.

Main research question: We aim to determine whether cerebral NIRS or renal region NIRS could predict the postoperative incidence of AKI.

Design (including population, confounders/outcomes): Prospective observational pilot study, this is a non-WMO study. The population is infants and children below 18 years of age with non-cyanotic with a left to right shunt congenital heart disease. The outcome is postoperative AKI, defined using the KDIGO criteria (blood creatinine and urine output).

Study objective

We hypothesize that lower renal region or cerebral NIRS values are correlated with a higher incidence of postoperative AKI in this study population

Study design

Multiple; Continuous monitoring intraoperative

Intervention

None

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

Infants and children (0-18 years)

Undergoing elective cardiac surgery with cardiopulmonary bypass for correction of non-cyanotic, left to right shunt congenital heart disease

Exclusion criteria

Pre-existing renal disease (mentioned in the patient history or preoperative serum creatinine >100 µmol/L)

Structural renal diseases/abnormalities

Pre-existing cerebral disease (mentioned in the patient history)

Limitations in the positioning of NIRS sensors (for example skin defects or diathermia pad placement)

Extreme prematurity (gestational age <32 weeks)

Known or suspected allergies to glue of the adhesive NIRS sensors

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	27-10-2021
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion	
Date:	27-10-2021
Application type:	First submission

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
NTR-new	NL9852

Register

Other

ID

METC UMCG : METc 2021/191

Study results