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

Gepubliceerd: 27-10-2021 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23984

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Non-cyanotic, left to right shunt congenital heart disease

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

Multiple; Continuous monitoring intraoperative

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

University Medical Center Groningen
C Niezen

0503616161

Wetenschappelijk

University Medical Center Groningen
C Niezen

0503616161

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	27-10-2021
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	27-10-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9852
Ander register	METC UMCG : METc 2021/191

Resultaten