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Near-infrared spectroscopy to monitor cerebral and renal oxygen saturation during cardiopulmonary bypass surgery for paediatric congenital heart disease: study protocol for a prospective observational cohort trial

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ABSTRACT

Background Current indicators for monitoring intraoperative organ function remain predominantly indirect, delayed and non-specific, particularly in paediatric populations undergoing congenital heart surgery, where multifactorial influences further complicate functional assessments. Emerging evidence suggests that the use of near-infrared spectroscopy (NIRS) technology to continuously monitor the regional oxygen saturation (rSO_2) of intraoperative organs can predict the postoperative organ functional status. This study aims to investigate the associations between intraoperative cerebral/renal rSO_2 fluctuations monitored by NIRS and postoperative neurological injury or acute kidney injury (AKI) in paediatric congenital heart disease (CHD) surgery.

Methods and analysis In this prospective observational cohort study, patients ≤18 years, scheduled for CHD surgery under cardiopulmonary bypass (CPB), will be enrolled after obtaining written informed consent. Exclusion criteria include pre-existing neuropsychiatric disorders, chronic kidney disease or other related disorders. Dual-channel NIRS probes will be applied to simultaneously monitor cerebral and renal rSO_2 from anaesthesia induction until the patient is transferred to the cardiac care unit. Serum S100 calcium-binding protein B (S100B) levels will be measured before CPB, at the end of the surgery and on postoperative day 1 to quantify cerebral injury. AKI will be diagnosed using the paediatric risk, injury, failure, loss, end-stage renal disease (pRIFLE) criteria based on dynamic creatinine changes. Health-related quality of life will be assessed through the paediatric quality of life (PedsQL) inventory at preoperative baseline and postoperative day 30.

Ethics and dissemination This study has been approved by the Institutional Review Board of Beijing Children's Hospital (approval number: [2024]-Y-093-D). Prior to enrolment, written informed consent will be obtained from the parents or legal guardians of all participating minors. The findings of this research will be disseminated through peer-reviewed publications and presentations at relevant conferences and shared with participating communities via lay summaries and social media platforms.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a prospective cohort study designed to adjust for confounders using regression methods to determine the relationship between regional oxygen saturation and organ injury.
⇒ The study includes detailed monitoring of cerebral and renal oxygen saturation using near-infrared spectroscopy throughout the perioperative period, including desaturation and oversaturation events.
⇒ Multiple prognostic indicators, such as quality-of-life scores, length of hospital stay and hospitalisation costs are incorporated into the analysis.
⇒ The study is limited by its single-centre design, which may affect the generalisability of the findings.
⇒ Data collection relies on continuous near-infrared spectroscopy monitoring, which may be subject to technical limitations such as sensor detachment or signal interference.

Trial registration number The study was registered with the Chinese Clinical Trial Registry on 18 April 2024 (ChiCTR2400083225).

BACKGROUND

The intraoperative monitoring of oxygen delivery and consumption in paediatric vital organs faces unique challenges owing to developmental factors, including age-dependent physiological variability, body size limitations and haemodynamic instability. Conventional perioperative indicators, such as lactic acidosis, hypothermia, bradycardia, hypotension and oliguria, though routinely monitored perioperatively, provide only indirect and non-specific warnings of incipient organ dysfunction. NIRS has emerged as a non-invasive modality for real-time monitoring of regional tissue oxygen saturation

(rSO_2) in both surgical and critical care settings. Accumulating evidence delineates its clinical applications across multiple organ systems.[1 2] There are studies on brain tissue oxygen saturation, abdominal oxygen saturation and renal oxygen saturation. Some studies have described trends in normal values of rSO_2 in the brain and internal organs of preterm infants, and changes in rSO_2 indices over time may be indicative of the maturation of physiological oxygen balance in this tissue.[3 4] In children, cerebral rSO_2 below a certain level from baseline during non-cardiac surgery can lead to adverse behavioural changes or delirium in the postoperative period.[5 6] It has been suggested that reduced renal rSO_2 in preterm infants is associated with AKI, which is an independent risk factor for mortality and morbidity in hospitalised patients and can lead to chronic kidney disease and adverse long-term health problems. Notably, cerebral and renal functional integrity constitutes pivotal prognostic determinants in paediatric postoperative outcomes.

Altering the state of organ perfusion, oxygen delivery and energy expenditure can prevent or promote cellular damage (from oxidative stress and inflammation) and recovery, a state that occurs during cardiac surgery under CPB. Brain regional oxygen saturation, which is characterised by high constant blood flow and high oxygen uptake, and renal tissue oxygen saturation, which is characterised by high blood flow variability and relatively low oxygen uptake, have the potential to be disrupted during cardiopulmonary bypass. In the present study, cerebral/renal rSO_2 monitoring will be continuously performed during surgery for CHD in children and an attempt will be made to investigate its relationship with brain injury and AKI. To evaluate the association between rSO_2 and quality of life after surgery and anaesthesia, the paediatric quality of life (PedsQL) survey will be given to caregivers on the day of surgery (baseline) and 30 days after surgery.[7]

METHODS

Study design

This is a prospective, observational, cohort study. This study has been approved by the ethics committee of Beijing Children's Hospital ([2024]-Y-093-D, protocol amendment number:4.0, issue date: 27 March 2024) and is registered in the Chinese Clinical Trial Registry (ChiCTR2400083225). We will strictly adhere to clinical practice guidelines and the Declaration of Helsinki throughout the trial. Participants will include paediatric patients (age ≤18 years) undergoing CHD surgery requiring CPB. Written informed consent will be obtained from legal guardians prior to enrolment.

Objectives

The primary objective is to determine the relationship of cerebral and renal oxygen saturation to brain injury and kidney injury. The secondary objectives are to determine the perioperative factors associated with brain injury and kidney injury and to explore the effects of brain injury and kidney injury on patients' quality of life.

Sample size

The sample size calculation is based on the primary objective of evaluating the relationship between cerebral rSO_2 changes and brain injury. Ten clinically relevant covariates will be included in the multivariate regression model: age, sex, weight, risk adjustment for congenital heart surgery-2 (RACHS-2) category, preoperative cyanosis status, baseline haematocrit, left ventricular ejection fraction (LVEF), rSO_2, CPB duration and mean arterial pressure during CPB. Using the multiple regression module in PASS 15.0, the calculation assumes a target coefficient of determination (R^2) of 0.25 with an anticipated effect size of R^2=0.5. With α=0.05 and 90% power, the minimum required sample size is determined to be 117 participants after accounting for 20% attrition (attributable to withdrawal or data collection errors).

Eligibility criteria

Inclusion criteria:[1] Age ≤18 years.[2] To be operated under CPB for corrective surgery of congenital heart disease.[3] Parental or guardian's permission (signed informed consent). Exclusion criteria:[1] Post-menstrual age ≤38 weeks.[2] Renal disease or renal insufficiency.[3] Neuropsychiatric disorders (autism, developmental delay, cognitive impairment).[4] Heart transplantation, preoperative dialysis, infection, sepsis, preoperative extracorporeal life support, use of contrast media within 7 days before surgery.

Study procedures

The flow of the study is shown in figure 1. A baseline PedsQL will be administered to caregivers on the day of surgery. A repeat assessment will be conducted at postoperative day 30. All patients will receive standard anaesthetic protocols as determined by the attending anaesthesiologist. Continuous rSO_2 measurements will be acquired from operating room admission until transfer to the cardiac intensive care unit. The SenSmart Model X-100 Universal Oximetry System (Nonin Medical, Plymouth, MN, USA) will be used to record cerebral and renal rSO_2 values at 4 s intervals. Fraction of inspired oxygen will be maintained at 100% throughout the surgery. The forehead and right kidney regions will be inspected for lesions or abrasions prior to electrode application. Under ultrasound guidance, one NIRS sensor electrode will be positioned on the right paravertebral region (T10-L2 vertebral levels), and the other sensor electrode is placed over the forehead and connected to the monitor to start recording rSO_2 data. To avoid electrode detachment, the renal region electrode can be covered with a 3M film and the forehead electrode can be wrapped with an elastic bandage.

Measurement of cerebral rSO_2 (C-rSO_2) and renal rSO_2 (R-rSO_2)

Real-time rSO_2 values will not be accessible to the anaesthesia or perfusion teams to prevent intervention bias.

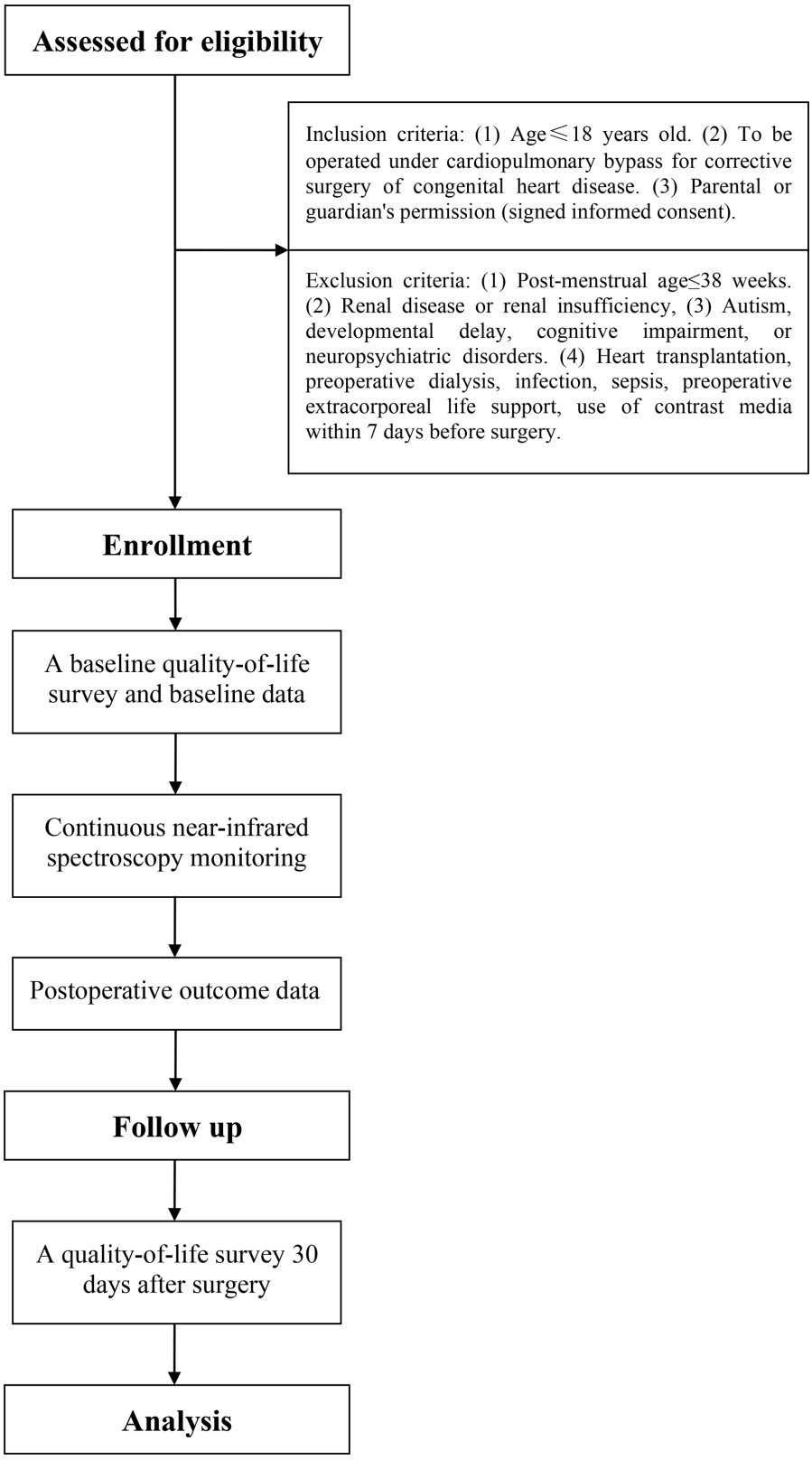

Figure 1 Flow diagram of the patients in the study.

Three distinct perioperative phases will be analysed: Phase 1: preinduction baseline. Phase 2: CPB duration. Phase 3: post-CPB period. All 4s interval measurements within each phase will be averaged to compute mean C-r-SO_2/R-rSO_2. We also will evaluate cumulative time spent during CPB at or below a rSO_2 value 10% less than baseline (desaturation) and cumulative time spent at or above a rSO_2 value 10% more than baseline (oversaturation). The 10% threshold for cerebral rSO_2 desaturation is based on established evidence in paediatric populations. Although

adult studies suggest that a 20% decrease from baseline cerebral rSO_2 is associated with postoperative cognitive dysfunction,[8] paediatric brains exhibit greater sensitivity to hypoxia. Therefore, we adopted a more conservative threshold of 10%, consistent with Holmgaard *et al*.'s methods in children undergoing cardiac surgery.[9]

Definition of brain and kidney injury

To recognise brain injury, one method is to assess the concentration of specific markers in plasma, among which the most studied in the paediatric population is S100 calcium-binding protein B (S100B), which is the most abundant calcium-binding protein in neural tissues (especially astrocytes) and is one of the injury-associated molecules released early in brain injury or after primary brain injury, which can lead to secondary injury.[10] S100B is considered a biomarker of traumatic brain injury and has been shown to correlate with the extent of injury, survival and neurological prognosis.[11] Serum levels of S100B protein are elevated in patients with brain injuries induced by trauma, haemorrhage and ischaemia, and therefore S100B is often used as a biomarker to assess the severity and prognosis of brain injuries.[12] Three-time points are selected for S100B measurement: pre-CPB (baseline), immediate postoperative and on first postoperative day.

Acute kidney injury after congenital heart surgery (paediatric cardiac surgery-associated acute kidney injury, PCS-AKI) is a common complication in children, with reported incidence ranging from 40% to 60%.[13–15] PCS-AKI is an independent risk factor for mortality and morbidity in hospitalised patients[16–18] and can lead to chronic kidney disease and adverse long-term health problems.[19 20] The diagnostic criteria for AKI in children in the present study used the pRIFLE system (the paediatric risk for renal dysfunction, injury to the kidney, failure of kidney function, loss of kidney function and end-stage renal disease), which is a classification based on estimated creatinine clearance and urine output as criteria and has been validated in paediatric cardiac surgery patients. The pRIFLE system is the most sensitive indicator for detecting AKI, and it is particularly suitable for the early recognition of AKI in infants, young children and low-risk patients.[21] AKI is categorised as stage I (risk), stage II (injury) and stage III (failure). These stages correspond to a decrease in glomerular filtration rate of 25%, 50% or 75%, respectively. Baseline serum creatinine (SCr) will be measured within 48 hours preoperatively. The postoperative maximum level of SCr will be obtained within 4 days after surgery.

Study duration and safety

Participation in the study begins with submission of the baseline PedsQL questionnaire and ends with completion of the follow-up PedsQL questionnaire. The patient's caregivers are free to withdraw the child from the study at any time. As this is a very low-risk observational study, there are no guidelines for ending the study early, and the safety data (if applicable) will be summarised.

Definitions of study objectives and other terms

Primary study objective

To comprehensively evaluate the association between intraoperative rSO_2 fluctuations and organ injuries, five quantitative metrics will be analysed. (a) Occurrence of brain and kidney injuries; (b) a mean rSO_2 for before, during and after CPB periods; (c) total duration of all desaturation or oversaturation; (d) percentage of total desaturation or oversaturation time over total CPB time and (e) area-under-the-curve (AUC) for rSO_2 deviations from baseline, calculated separately for each phase and the entire surgical period.

Secondary study objectives

Identify perioperative factors associated with injury to the brain and kidney. Such factors include patient, anaesthetic, surgical and physiological factors as mentioned in section variables for analyses. Also, determine whether the brain and kidney injuries are associated with postoperative changes in quality-of-life scores.

Definition of study periods

NIRS monitoring will be performed continuously from anaesthesia induction until surgery completion. For analytical purposes, the following phases are defined: pre-CPB: from anaesthesia induction to the onset of CPB; CPB: from the onset to the end of CPB; post-CPB: from the end of CPB to completion of the surgery.

Variables for analyses

Patient factors

- Gender (M/F)
- Age at study (months)
- Height (cm)
- Weight (kg)
- American Society of Anesthesiologists physical status
- Preoperative haemoglobin and haematocrit level
- Preoperative SCr
- Preoperative left ventricular ejection fraction
- Cyanotic lesions (yes/no)

Surgical factors

- Type of surgery: ventricular septal defect repair, patch or primary closure; atrial septal defect repair; tetralogy of Fallot repair, with or without ventriculostomy; total anomalous pulmonary venous connection repair; double outlet right ventricle repair; others.
- RACHS-2 is a new approach to identifying and risk-stratifying paediatric cardiac surgery using ICD-10 administrative data.
- CPB and aortic cross-clamp time
- Number of attempts to end CPB.
- Ventricular fibrillation during weaning.
- Extubation time.

Table 1 Demographic and clinical characteristics of the participants

Patient characteristics	All patients	rSO_2 desaturation*	rSO_2 oversaturation†	P value
Male				
Female				
Age (months)				
Height (cm)				
Weight (kg)				
ASA physical status				
1				
2				
3				

*Desaturation: below an rSO_2 value 10% less than baseline.
†Oversaturation, above an rSO_2 value 10% more than baseline.
ASA, American Society of Anesthesiologists.

Anaesthetic factors

Standard anaesthetic medications, including propofol, midazolam, opioids and end-tidal sevoflurane concentrations, will be recorded and adjusted for as covariates in the analysis.

Physiological factors

Oxyhaemoglobin saturation (SpO_2), mean arterial pressure, temperature, urine output, haemoglobin and haematocrit during CPB.

PedsQL survey

An age-appropriate PedsQL questionnaire will be given to caregivers on the day of surgery and 30 days after surgery. Each question will be scored on a 5-point scale, with the lower the score, the better the 'quality of life'.

- Survey for 1–12 months: 36 questions divided into physical functioning (6 questions), physical symptoms (10 questions), emotional functioning (12 questions), social functioning (4 questions) and cognitive functioning (4 questions).
- Survey for 13–24 months: 45 questions divided into physical functioning (9 questions), physical symptoms (10 questions), emotional functioning (12 questions), social functioning (5 questions) and cognitive functioning (9 questions).
- Survey for 24+ months: 27 questions divided into physical functioning (8 questions), emotional functioning (5 questions), social functioning (5 questions), school functioning, if applicable (3 questions), and cognitive functioning (6 questions).

Prognostic indicators

- Length of postoperative hospital stay.
- Hospitalisation expenditures.

Statistical analysis

Description of baseline data

Basic and population demographic characteristics are summarised using standard descriptive statistics (eg, mean (SD) or median (IQR) for continuous variables such as age and percentages for categorical variables such as sex).

Analysis of the primary objective

All subjects who meet the inclusion and exclusion criteria and complete the study will be included in the primary analysis. Descriptive statistics will be used to analyse the primary endpoints throughout anaesthesia and for each surgical stage.

1. Occurrence (%) of brain and kidney injuries.
2. A mean rSO_2 (IQR) for before, during and after CPB periods.
3. Total duration (IQR) of all desaturation or oversaturation.
4. Percentage (IQR) of total desaturation or oversaturation time over total CPB time.
5. The AUC of desaturation or oversaturation (IQR).

Analysis of secondary study objectives

A continuous variable will be created for change in S100B protein and a binary outcome variable will be created for the presence or absence of an acute kidney injury event (yes/no) based on the criteria defined in the primary objective. To identify perioperative factors associated with the change in S100B protein and acute kidney injury, we will use the χ^2 test or Fisher's exact test for categorical variables and the two-tailed independent samples t-test or the Wilcoxon rank sum test for continuous variables, as appropriate. We will accept a Type I error rate (α) of no more than 0.05.

We will then select variables with p values less than 0.1 from the univariate analyses to build multivariate linear regression models and logistic models, respectively, to adjust for confounders. In order to test the association between changes in cerebral/renal oxygen during CPB and the results of the PedsQL survey, a multilevel analysis will be performed. In addition to the main predictor, AUC of desaturation or oversaturation, quality of life scores

Table 2 Perioperative variables and outcomes

	All patients	rSO_2 desaturation*	rSO_2 oversaturation†	P value
Outcomes				
Changes in S100B				
PCS-AKI				
Preoperative variables				
Prehaemoglobin				
Prehaematocrit				
Pre-SCr				
Pre-LVEF				
Precyanotic lesions (yes/no)				
Pre-S100B				
Type of surgery				
VSD				
ASD				
TOF				
TAPVC				
DORV				
Others				
RACHS-2				
Pre-PedsQL score				
Anaesthetic drugs				
Propofol				
Midazolam				
Opioid				
End-tidal of sevoflurane				
Intraoperative variables				
CPB and aortic cross clamp time				
Aortic cross clamp time				
Number of attempts to end CPB				
Ventricular fibrillation during weaning				
SPO_2 during CPB				
MAP during CPB				
Temperature during CPB				
Urine output during CPB				
Haemoglobin during CPB				
Haematocrit during CPB				
Postoperative variables				
Post-SCr				
Post-S100B				
Extubation time (hour)				
Hospitalisation costs				
Post-PedsQL score				

*Desaturation: below an rSO_2 value 10% less than baseline.
† Oversaturation, above an rSO_2 value 10% more than baseline.
ASD, atrial septal defect repair; CPB, cardiopulmonary bypass; DORV, double outlet right ventricle repair; LVEF, left ventricular ejection fraction; MAP, mean arterial pressure; PCS-AKI, paediatric cardiac surgery-associated acute kidney injury; PedsQL, paediatric quality-of-life; RACHS-2, Risk Stratification for Congenital Heart Surgery for ICD-10 Administrative Data; rSO_2, regional oxygen saturation; S100B, S100 calcium-binding protein B; SCr, serum creatinine; TAPVC, total anomalous pulmonary venous connection repair; TOF, tetralogy of Fallot repair; VSD, ventricular septal defect repair.

Table 3 rSO_2 measurement during surgery

	All	Baseline	Pre-CPB	CPB	Post-CPB
Mean of rSO_2					
Desaturation rSO_2 events					
Minimum level					
Total duration					
Percentage of desaturation/total time					
Desaturation AUC					
Oversaturation rSO_2 events					
Maximum level					
Total duration					
Percentage of oversaturation/total time					
Oversaturation AUC					

AUC, area-under-the-curve; rSO_2, regional oxygen saturation.

may be influenced by other factors. These factors include, but are not limited to, general medical condition, type of surgery, postoperative extubation time and ICU length of stay, all of which may be confounders. Therefore, we will assess the relationship between baseline (day of surgery) quality of life scores and these factors using two-sample t-tests, analysis of variance, Pearson's correlation coefficient or non-parametric alternatives (eg, Wilcoxon's rank sum, Kruskal-Wallis ANOVA or Spearman's rank correlation), as appropriate. If the p value of the test was less than 0.1, the factor was added to the model as a covariate.

A sensitivity analysis will be performed to test the robustness of the results in order to account for loss to follow-up, using patients with complete PedsQL follow-up measures.

Selection bias

To evaluate potential selection bias, we will conduct a retrospective comparison of baseline characteristics, including age, RACHS-2 score, preoperative LVEF and other relevant variables, between enrolled patients and non-participants from the same surgical cohort.

Patient and public involvement

Participants in this study are given the opportunity to provide feedback on the study visit (ie, the visit is too long, too many question entries). In addition, at the end of the baseline visit, we will conduct a survey asking study participants about their current quality of life. We will continue to share study results and updates with participants both online and in person. The purpose of the interviews is twofold: to disseminate study results and to provide participants with the opportunity to ask about their research interests and priorities.

Ethics and dissemination

This study has been approved by the Institutional Review Board of Beijing Children's Hospital (approval number: [2024]-Y-093-D) and strictly adheres to the Declaration of Helsinki. Prior to enrolment, written informed consent will be obtained from all participants after detailed disclosure of study objectives, potential risks and benefits. Participant confidentiality will be ensured through restricted access to anonymised data by authorised investigators only. Participants retain the right to withdraw from the study at any time without penalty. As an investigator-initiated academic trial, the financial compensation is not feasible owing to funding limitations. However, participants experiencing treatment-emergent adverse events will receive free medical management at our institution. The results of this research will be presented at academic conferences and published in peer-reviewed journals. The International Committee of Medical Journal Editors guidelines on authorship criteria will be followed, and the manuscript will be drafted and edited by the authors, not by any professional writers.

DISCUSSION

Organ injuries, particularly neurological and renal complications, remain a significant concern in paediatric cardiac surgery, contributing to increased morbidity, mortality and healthcare resource utilisation.[22–24] It is known that intraoperative cerebral hypoperfusion and ischaemia are recognised as potential contributors to long-term cognitive impairment in infants. Despite the widespread use of NIRS for cerebral oxygenation monitoring, its ability to predict perfusion deficits and subsequent cognitive dysfunction remains controversial. One paediatric study demonstrated that lower mean intraoperative cerebral rSO_2 values were associated with unfavourable neurological outcomes.[25] Nevertheless, a large international multicentre study suggested that cerebral desaturation is unlikely to fully explain postoperative cognitive dysfunction.[24] Similarly, the relationship between intraoperative renal oxygenation and postoperative AKI is

inconsistent. Higher average renal rSO_2 during CPB has been linked to an increased risk of PCS-AKI.[26] Conversely, another study reported that decreased intraoperative renal saturation was associated with higher odds of AKI in infants.[27] In summary, organ functional status is influenced by multifactorial determinants, including the delicate balance between oxygen supply and demand. The predictive utility of intraoperative NIRS monitoring for organ outcomes requires further validation through well-designed prospective studies. The identification of reliable NIRS thresholds for organ protection could significantly improve perioperative management strategies in paediatric cardiac surgery.

REPORTING OF STUDY RESULTS

See tables 1–3. The results for cerebral rSO_2 and renal rSO_2 are reported separately, according to the tables.

TRIAL STATUS

The protocol version number is 3.0, and the protocol date is 7 March 2024.

The date recruitment began on 22 April 2024, with an approximate date of July 2025 for completion of recruitment.

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Contributors ZZG: Study design, data collection and manuscript write-up. JMZ: Study design, analysis and interpretation of data. LJL and FW: Study design, data analysis and critical manuscript revision. ZKG: Study design and data collection. XXW and LH: Data collection and analysis and write up of the manuscript. All authors read and approved the final manuscript. ZZG is the guarantor of the study, taking responsibility for the integrity of the work as a whole, from inception to published article.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

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