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Temperature monitoring using a urinary bladder catheter in children

Submission date
01/09/2020

Recruitment status
No longer recruiting

Registration date
13/10/2020

Overall study status
Completed

Last Edited
04/01/2023

Condition category
Surgery

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The aim of this study is to assess the accuracy of a special type of urinary catheter to monitor central body temperature. Both high and low body temperature have a detrimental effect on various organs such as the heart, blood clotting ability or the ability to fight infections, especially in children who are extremely ill or have major body stresses (e.g. undergoing a heart operation). Currently, a temperature measuring tube (catheter) is placed in the food pipe (oesophagus). This may cause pain and discomfort along with other complications such as perforation, trauma, bleeding or incorrect placement. Other common sites such as axillary, aural (ear) or skin temperature using an electronic or chemical dot thermometer are found to be inaccurate.
All children undergoing cardiopulmonary bypass for heart surgery (and most critically ill children) require a tube in their urinary bladder (urinary catheter) to help with urine flow and to measure urine volume. Special urinary catheters are now commercially available which can measure body temperature in addition to allowing urinary flow, so no additional invasive procedure is required. Current evidence in adults finds this to be an accurate alternative. However, there is no clear evidence for or against their use in children especially during conditions of reduced urine flow seen commonly after heart operations. Therefore, the researchers wish to perform this study.

Who can participate?
Children aged 4 months to 16 years or weight over 6 kg, undergoing open heart surgery

What does the study involve?
Once the parents/carer and the child agree to take part in the study, the following steps will happen. Before the operation the special temperature sensing urinary catheter is inserted which will drain urine and measure temperature at the same time. This will be a replacement for a standard urinary catheter which is inserted in every child undergoing open-heart surgery. During the operation and while the patient is recovering in the cardiac intensive care unit (CICU), the researchers will monitor their temperature from the oesophagus (standard practice) and urinary bladder (study-specific) simultaneously every 10 minutes for a total of 8 hours. Temperature is also monitored from the ear (study-specific) and axillary sites (standard practice) every 60 minutes for a total of 8 hours. Information is collected about how much treatment support the child is getting and how well their body organs are working, especially the lungs, heart, kidney

and brain, every 60 minutes. This information is routinely collected every hour as part of standard clinical care. Information is collected about the type of surgery and time(s) spent during various stages on the heart-lung bypass machine (standard practice). The total study period is 8 hours divided between operation theatres and cardiac intensive care unit (CICU); for example, if the operation lasts 2 hours in the theatres, the researchers will continue to study for another 6 hours in CICU. All the information mentioned above will be collected from electronic records without the parents/carers having to worry about spending time with the research team. Everything else about the operation, and care after the operation will happen in the normal way. The child will not have to stay any longer in the hospital for this study. After the child goes home, his/her treatment will not be different from others. There is no follow up for the purpose of the study.

What are the possible benefits and risks of participating?
The information collected will help to treat children undergoing heart operations better in the future. Taking part in this study will not benefit the participating child directly. The researchers do not expect any significant extra risks (compared to routine) to the child as a result of them taking part in this study and it will not affect the recovery of the child. The risks or complications of inserting this special urinary catheter with thermistor probe are the same as for insertion of a standard urinary catheter or other temperature measuring probe (such as oesophageal probe) for the purpose of the heart operation.

Where is the study run from?
Great Ormond Street Hospital for Children NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2019 to January 2023

Who is funding the study?
Paediatric Intensive Care Society (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
277776

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 44585, IRAS 277776

Study information

Scientific Title
Comparison between temperature-sensing Foley urinary catheter and oesophageal temperature probe for measurement of core body temperature in children undergoing open-heart surgery – an observational study

Study objectives
Urinary bladder temperature sensing catheters will be in agreement with the oesophageal temperature monitoring system without any effect of urinary flow rates.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval pending, Office for Research Ethics Committees (REC) Northern Ireland (ORECNI, Business Services Organisation, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, LISBURN, Co. Antrim, BT28 2RF, N. Ireland; Tel: not available; RECA@hscni.net), ref: 20/NI/0101

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)

Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Children undergoing open-heart surgery

Interventions
This is a single-centre, prospective, observational, proof-of-concept study with an aim to enrol 50 children. The study is expected to run over 18 months.

Method of recruitment:
(a) Children undergoing non-urgent or routine heart surgery: A parent invitation letter and parent/child information leaflet will be sent to the parents of all these children who are greater than 4 months old along with the outpatient appointment letter. Most of these children will attend an outpatient day where they meet with their medical/surgical teams and undergo investigations in preparation for their heart surgery. This will be coordinated by the surgical booking office team.

A member of the research team will be available on the day of the child's outpatient appointment to explain the study to the parents and child and answer any questions. The parents /children may decide to give consent/assent on that day itself. Some of the families may need additional time to think about it further. These families/parents/child can be re-engaged on the admission day prior to the operation date. This is typically 24-36 hours before the operation.

(b) Urgent or emergency admissions in Cardiac Intensive Care /Cardiology ward: Children already admitted to these clinical areas can be identified by respective clinical teams and information passed on to the research team as both teams work very closely. Research teams can also identify potential participants by screening through the patient dashboard list on electronic patient records (age and diagnosis).

Following this, the research team will approach the parent/carer and/or child with all the study-related relevant information. The researchers endeavour to provide a minimum of 24 hours time period from the point of first contact for families to think about the study and give consent. In an extremely small number of emergency cases this time period may be less than 24 hours.

Once the parents/participant understand the details of the study and are happy to join the study the researchers will ask them to sign an assent/consent form before the operation.

What will happen to the research participants:
1. Recording of demography details (preoperatively): date of birth, sex, NHS number, height, weight
2. Recording procedure details (postoperatively): diagnosis, name of the operation, duration of cardiopulmonary bypass, X clamp and DHCA
3. Preoperative on the day of surgery (in anaesthetic room) Insertion of age and weight appropriate special thermistor tipped Foley’s urinary catheter and oesophageal temperature probe (Insertion of the oesophageal temperature probe and a normal Foley's catheter is part of the standard care in these children)
4. Continuous monitoring of temperature from the urinary bladder and oesophageal sites with

simultaneous recording every 10 minutes during the intraoperative period followed thereafter in cardiac ICU for a total of 8 hours from the time of the start of the study (time of the first perioperative paired reading) (frequency=continuous)
5. Temperature recording from aural (ear) and axillary sites every 60 minutes: Opportunistic in theatres due to access issues- for a total of 8 hours from the start of the study (frequency = a total of 9 times over study period) (study-specific) (use of axillary site for hourly temperature monitoring in cardiac ICU is standard care)
The following details will be recorded every 60 min for a total of 8 hours from the time of the start of the study (frequency = a total of 9 times over study period, could be more in case of severe haemodynamic derangements) (60-minute recording is standard clinical care)
6. Respiratory status: cuffed or uncuffed endotracheal tube (ET), size of ET, mode of ventilation, peak inspiratory pressures, positive end expiratory pressure, inspiratory time, oxygen content of the inspiratory flow and tidal volume
7. Cardiovascular status including heart rate, blood pressure, central venous pressure, peripheral oxygen saturations
8. Details re inotrope infusion rate, fluid boluses (timing and volume), pacing
9. Neurological status: sedation, paralysis and pupillary reaction
10. Urine output
11. Use of external cooling/heating device
12. Timing and volume of any fluid boluses or requirement for a start or increase in inotropic or vasopressor support, greater than an increment of 2.5 µg/kg/min for dopamine or 0.05 µg/kg /min for adrenaline or noradrenaline (additional readings of the above parameters may be recorded at the same time point)

Everything else about the operation, and care during or after the operation will happen in the standard way. The child will not have to stay any longer than normal in the intensive care unit or the hospital as a result of this study.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Temperature sensing Foley’s urinary catheter

Primary outcome measure
1. Urinary bladder temperature measurement using a temperature sensing Foley’s urinary catheter at baseline then every 10 minutes for a further 8 hours
2. Oesophageal temperature measurement using a routine central temperature measuring probe at baseline then every 10 minutes for a further 8 hours

Secondary outcome measures
1. Axillary (using an electronic thermometer) and aural temperature (using an infrared ear thermometer) measured at baseline and every hour for a further 8 hours
2. Urinary output measured using a standard graduated urine collection bag at baseline and every hour for a further 8 hours

Overall study start date
16/08/2019

Completion date
14/01/2023

Eligibility

Key inclusion criteria
1. Age and weight appropriate for urinary catheterisation of size 8 Fr and above (age > 4 months and less than 16 years or weight >6 kg for size 8Fr urinary catheter)
2. Open heart surgery with cardiopulmonary bypass
3. Informed consent to participate

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Months

Upper age limit
16 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Key exclusion criteria
1. Age greater than or equal to 16 years
2. Recent history of oesophageal or urinary bladder surgery (less than 4 weeks)
3. Contraindication for urethral catheterisation due to anatomical malformations, urethral obstruction or haemorrhage
4. Generalised bleeding state immediately prior to the cardiac surgery
5. A recent history of otitis media or discharge from both ears (<7 days before surgery)

Date of first enrolment
15/01/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Great Ormond Street Hospital for Children NHS Foundation Trust
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Sponsor information

Organisation
Great Ormond Street Hospital for Children NHS Foundation Trust

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.gosh.nhs.uk/

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Paediatric Intensive Care Society

Results and Publications

Publication and dissemination plan
Additional documents such as study protocol will be made available. Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No