ISRCTN12937489 https://doi.org/10.1186/ISRCTN12937489

RECOGNISE: Using a Cerebral Oximeter monitoring device to identify and reduce postoperative complications in cardiac surgery

Submission date 11/12/2017	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 09/01/2018	**Overall study status** Completed	
Last Edited 07/04/2020	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Cardiac surgery involving cardiopulmonary bypass (a technical that takes over the heart and lungs to circulate blood during surgery) carries with it a significant incidence of delirium (a state of extreme confusion) and cerebrovascular accident (or stroke). The cerebral oximiter is a monitoring device that can be used in addition to other monitoring devices. It is already currently used within UHSM as part of standard care at the discretion of the anaesthetist, however currently only in higher risk patients. The cerebral oximiter uses Near infra red spectroscopy (NIRS) to assess the bifrontal regional cortical oxygen saturation and has been shown to have a relationship with stroke during surgery and delirium. It is also possible that, by using the brain as the index organ, the NIRS could identify a decrease in oxygen saturation in other organs – that is when the brain has a deficit of oxygen supply it is reasonable to expect that other organs, for example the kidneys, also do. In this case increasing the oxygen supply to the brain would also increase the oxygen supply to other organs and prevent their dysfunction. The aim of this study is to see if cerebral oximeter, which uses NIRS can improve outcomes for patients who are assessed as being at medium risk of experiencing confusion or other complications following cardiac surgery.

Who can participate?
Adults aged 18 and older who are due to undergo elective or urgent cardiac surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants are asked to complete the Rey Auditory Verbal Learning Test (RAVLT). Those in use the cerebral oximeter but in a mode where the data is recorded but alters the screen and does not compare data. Those in the second group use the cerebral oximeter fully and this can alert the anaesthetists. Clinical outcomes are recorded for the duration of the stay on the intensive care unit. Participants are followed up around six to 12 weeks to repeat the RAVLT test. At this point, the participant is unblinded and the study group is discussed with the participant. Near infra red spectroscopy (NIRS)

What are the possible benefits and risks of participating?
The study may benefit the patient if the patient is randomised to the interventional group, and the cerebral oximeter shows a drop in cerebral saturation >20% from baseline as the interventional algorithm may be triggered sooner than by clinical judgement alone, thus the patient may benefit from improved outcomes. By being part of the study, this research aims to benefit patients of the future by introducing cerebral oximetry into routine use for all patients undergoing cardiac surgery to improve outcomes. This trial has been assessed for risk and assessed as a medium risk category. However, the INVOS 5100C cerebral oximeter is currently CE approved for marketed use and is currently in use within the hospital, in a higher risk group of patients. This study will recruit a lower risk group of patients therefore it is expected that this study will pose no additional risks to those already associated with cardiac surgery. There is already a standardised algorithm currently used during high risk cardiac surgery where an increased risk of cerebrovascular accidents is present. This includes a stepwise approach to improve the cerebral blood flow and/or reduce the cerebral metabolism. The standard algorithm used during cardiac surgery cases at high risk of cerebrovascular complications is very similar to this study algorithm. Oxygen levels are already currently measured as part of standard clinical care during cardiac surgery by metabolic parameters such as arterial blood gases which are checked hourly. The cerebral oximeter is an additional means of monitoring oxygen rates over and above what is currently already used. It is therefore considered that the study will pose minimal risk to the patient other than the risks already associated with their planned cardiac surgery.

Where is the study run from?
Wythenshawe Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2017 to June 2020 (updated 07/04/2020, previously: April 2020 (updated 14/10/2019, previously: December 2018))

Who is funding the study?
Medtronic Ltd. (UK)

Who is the main contact?
Ms Cathy Spence (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32738

Study information

Scientific Title
Routine usE of Cerebral Oximetry monitorinG iN cardIac SurgEry. A Randomised Controlled Single Centre Study to evaluate the use of neuromonitoring to identify and reduce postoperative complications

Acronym
RECOGNISE

Study objectives
This research is being done to see if we should use an additional monitoring device, known as a Cerebral Oximeter in all heart surgery patients. Currently, the device is only used for a small group of patients determined to be at higher risk of experiencing confusion or other complications following heart surgery.

The aim of the research study is to collect information from the operations of a wider group of patients, who have been assessed as medium risk of experiencing confusion or other complications following heart surgery. If the results of the research show these benefits, this could mean that the device is used routinely in the future for all patients in this group to help improve patient outcomes following heart surgery. The study will also record whether the device helps to reduce the length of stay in the intensive care unit following heart surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester Central Research Ethics Committee, 25/09/2017, ref: 17/NW/0504

Study design
Randomised; Both; Design type: Process of Care, Surgery, Validation of investigation /therapeutic procedures

Primary study design

Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Perioperative Medicine

Interventions
Participants are recruited pre operatively either at pre-operative clinic or at the anaesthetic visit immediately prior to surgery and are asked to complete the Rey Auditory Verbal Learning Test (RAVLT) administered by a research team member. Participants are studied by cerebral oximetry until extubation. After extubation the cerebral oximeter is disconnected. Clinical outcomes are recorded for the duration of the stay on the intensive care unit. In the usual participant this will be approximately 14 days however there will be some variation based on urgency of surgery and length of time on the intensive care unit. Participants are followed up 6-12 weeks (+/-7 days) following extubation and asked to repeat the RAVLT test. At this point, the participant is unblinded and the study group is discussed with the participant. This concludes the participant's inclusion in the trial.

Intervention Type
Other

Primary outcome measure
Comparison of the primary outcome measure, delirium rate, is measured using the Rey Auditory Verbal Learning Test both immediately prior to surgery and at 6-12 weeks (+/-7 days) following extubation.

Secondary outcome measures
1. Post-operative CerebroVascular Accident CVA confirmed by CT scan as per standard care at followup within two days of surgery.
2. Post-operative renal dysfunction measured using RIFLE Scoring
3. ITU length of stay measured using hospital records at discharge
4. Post-operative Cognitive Dysfunction measured using RAVLT at 6-12week follow up

Overall study start date
09/10/2017

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Participant is willing and able to give informed consent for participation in the study
2. Male or Female, aged 18 years or above at point of consent
3. Participant is due to undergo elective or urgent cardiac surgery
4. Able (in the Investigators opinion) and willing to comply with all study requirements

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 440; UK Sample Size: 440

Key exclusion criteria
1. Patients undergoing emergency cardiac surgery
2. Participant undergoing transplantation surgery or Mechanical Circulatory Support Implantation surgery.
3. Participants undergoing aortic surgery with Deep Hypothermic Circulatory Arrest
4. Patients already unconscious, sedated or anaesthetised before surgery
5. Patients unable to provide informed consent
6. Significant alcohol intake preoperatively (> 50 units/week)
7. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant’s ability to participate in the study

Date of first enrolment
01/03/2018

Date of final enrolment
31/03/2020

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital
Manchester University NHS Foundation Trust
Southmoore Road
Wythenshawe
Manchester
United Kingdom
M23 9QT

Sponsor information

Organisation
University Hospital Of South Manchester NHS Foundation Trust

Sponsor details
Wythenshawe Hospital
Southmoor Road
Wythenshawe
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England
United Kingdom
M23 9LT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
Medtronic Ltd.

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal at Feb 2020.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No