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A study comparing brain cooling method of conventional vs additional nasal cooling on aortic root surgery

Submission date
05/10/2014

Recruitment status
No longer recruiting

Registration date
04/11/2014

Overall study status
Completed

Last Edited
08/07/2021

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Surgery to fix the major blood vessel (the aorta) coming out from the heart is a complicated procedure and the risks of problems with the brain are fairly common following the surgery. Sometimes these problems can be mild and may only be present for a day or two but sometimes they can cause greater problems such as stroke and a prolonged or permanent period of confusion or reduced mental capabilities. To minimize these risks, patients are cooled down to very low temperatures during the procedure with the use of a heart lung machine, which protects the brain.
The aim of this study is to see if a machine called the RhinoChill can help protect the brain even more by a period of early brain cooling and a period of brain cooling towards the end of the operation. The RhinoChill is a machine that sprays a coolant liquid into the nose through a thin tube in each nostril. The cooling of the brain starts much early with this method and the brain is already cool before the heart lung machine is switched on. The RhinoChill will then be used again towards the end of the operation when the heart lung machine is warming the patient back up, but this time it will be used to try and rewarm the brain a little slower than the rest of the body, as a period of quick rewarming of the brain may also cause problems afterwards. It is believed that this period of early brain cooling and using the RhinoChill towards the end of the operation may help reduce problems once the patient wakes up.

Who Can Participate?
All patients, both men and women, of any age, who are going to be having this special type of heart surgery and who can understand the information required to decide to take part or not can be part of this study. We are looking to recruit 30 patients.

What does the study Involve?
Participants will be randomly allocated to one of two groups:
Patients undergoing the normal operation with all of the normal procedures in place.
Patients undergoing the normal operation with all of the normal procedures in place, but with the RhinoChill device being used before going onto the heart lung bypass machine and again when they are being warmed up again towards the end of the operation.

What are the possible benefits and risks of participating?
There is a possibility that early brain cooling and slower brain rewarming may reduce the chance of temporary or permanent brain problems after the operation, but this is not known yet.
When using the RhinoChill there is a small risk of a mild nosebleed (less than 10%), and a collection of fluid around the eyes (less than 1%) but these are known to be mild problems which get better quickly without any treatment. There is no additional risk or discomfort other than that associated with the operation itself.

Where is the study run from?
This study is being performed in only one hospital, the University hospital of South Manchester (UK).

When is the study starting and how long is it expected to run for?
From September 2014 until the 30th patient agrees to take part (expected to be around February 2016).

Who is funding the study?
All research costs are being paid by the University Hospital of South Manchester. The company that make the RhinoChill (Benechill International GmbH) are providing the RhinoChill Devices, the nasal tubes and the coolant liquid for free.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Randomised prospective pilot study comparing conventional brain cooling with early additional trans-nasal cooling prior to surgery on the ascending aorta/proximal aortic arch

Acronym
ARcTIC (Aortic RooT Intranasal Cooling)

Study objectives
It is well established that patients undergoing proximal aortic arch surgical procedures are at risk of both major and minor neurological complications. These complications range from temporary cognitive and neurological dysfunction (confusion, delirium, capacity to understand, poor mental status, decreased mobility and increased length of hospital stay) to permanent stroke and extensive brain damage. We hypothesise that the use of transnasal brain cooling prior to, during proximal aortic arch surgery and during rewarming (to reduce the speed of rewarming of the brain and prevent fever post rewarming) may reduce these complications. Purpose of this study: to assess whether the use of transnasal brain cooling has any impact on reducing the incidence of temporary and permanent neurological dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
GM West Ethics, 14/NW/0253

Study design
Single-centre randomised pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Surgery on the ascending aorta/proximal aortic arch

Interventions
The patients will be randomly allocated into two groups (15 in each group with 10% drop out) using computerised simple block randomisation.

Normal practice: Control Group 1

1. On arrival into the anaesthetic room, routine monitoring will be instituted, anaesthesia will be induced and endotracheal intubation performed
2. Insertion of a central line and bladder catheterisation will both be performed following anaesthesia and the patient will be prepared for surgery
3. A baseline tympanic temperature will be measured routinely
4. Arterial blood temperatures will be measured throughout the procedure
5. On commencement of heart and lung bypass the patients body will be cooled systemically to 15°C (occasionally to 12°C) and ice packed around the head for additional brain protection. IV thiopentone will be given for additional neuroprotection

6. Replacement of the ascending aorta/proximal aortic arch will be performed as usual. Depending on the exact nature of the procedure the aortic root may also be replaced
7. Any additional cardiac procedure performed at the same time will be recorded

For study purpose one group of patients will receive: Experiment Group 2

1. On arrival into the anaesthetic room, routine monitoring will be inserted, anaesthesia induced and the airway secured by endotracheal intubation
2. Once the airway is secured a baseline tympanic temperature will be measured
3. A Rhino Chill nasal catheter will be inserted into both nostrils of the patient and will be secured in place with the supplied head strap
4. Cooling will be commenced on high flow
5. Once the cooling is underway the central line will be inserted and the patient prepared for surgery
6. Due to the trans-nasal cooling procedure, standard nasopharyngeal temperature monitoring cannot be used
7. Tympanic temperature measurements will be taken at a minimum of every 10 minutes during induction of hypothermia
8. Once a target temperature of 34°C (tympanic) is achieved, the Rhino Chill flow will be adjusted to ensure brain temperature does not decrease below 32°C prior to cooling via the heart bypass machine
9. Once systemic cooling has reduced the core temperature to less than 25°C, the Rhino Chill will be turned off (the target temperature achieved by the cooling heart and lung bypass machine is usually 15°C, occasionally 12°C).
10. Once the systemic re-warming has achieved 25°C, the Rhino Chill will be turned back on to maintain a tympanic temperature of at least 1°C less than the core temperature during the rewarming phase
11. Once the re-warming target temperature of 36.5°C (core) has been achieved, the Rhino Chill will be continued as required to ensure the prevention of tympanic temperature greater than 36.0°C until the patient is moved to the intensive care department
12. When the patient leaves the operation theatre after surgery has been completed, the probe will be removed from the patient and patient will be covered with the routine warming blanket according to the local protocol

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Assess if transnasal brain cooling has any effect on reducing postoperative neurological dysfunction

Key secondary outcome(s))
1. Assess the effect of transnasal brain cooling on:
1.1. Early mobilisation
1.2. Length of hospital stay
1.3. Requirement of sedative medications for confusion and delirium
2. Assess the effect on brain and core temperature trends when trans-nasal brain cooling is used prior to and during deep hypothermia

Completion date
16/03/2016

Eligibility

Key inclusion criteria
1. All patients undergoing elective proximal aortic arch surgery with deep hypothermia circulatory arrest
2. Patients who have given written informed consent to take part in this study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who are not undergoing deep hypothermia circulatory arrest
2. Patients undergoing emergency operations
3. Refusal to take part in the study
4. Patients who have a history of epistaxis (nasal bleeding) requiring hospital intervention
5. Patients who have a history of nasal obstruction
6. Patients who have a history of deviated nasal septum
7. Patients who have a history of coagulopathy
8. Patients who have a history of liver dysfunction
9. Patients who have a history of renal dysfunction and also less than GFR 30

Date of first enrolment
04/08/2014

Date of final enrolment
03/02/2016

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

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Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust (UK)

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital of South Manchester NHS Foundation Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/07/2021	08/07/2021	No	No
HRA research summary			28/06/2023	No	No