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Manubrium-limited ministernotomy versus conventional sternotomy for aortic valve replacement

Submission date
15/01/2014

Recruitment status
No longer recruiting

Registration date
03/02/2014

Overall study status
Completed

Last Edited
01/02/2021

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Open heart surgery to replace one of the valves in the heart (the aortic valve) is a common NHS procedure. Patients needing this operation suffer symptoms of chest pain, shortness of breath and dizziness caused by the valve becoming narrow (aortic stenosis) or leaky (aortic regurgitation). To replace the valve, the operation usually involves cutting the breast bone completely (from the collar bone to the bottom of the breast bone); this is called a sternotomy. At least one in three patients who have this operation bleeds after the operation to the extent that they need a blood transfusion. This has risks for the patient such as difficulty breathing, confusion, an increased chance of getting an infection or dying, and a longer stay in hospital. A new operation has been developed which means that a much smaller part of the breast bone needs to be cut to replace the valve; this operation is called a manubrium-limited ministernotomy. Early results from our hospital suggest that fewer patients need a blood transfusion after a manubrium-limited ministernotomy than after a sternotomy. This means that patients may recover faster and be fit to go home sooner, which is better for patients and for the NHS. We now need more information to be sure whether or not the new operation is better. This study will compare the two operations in 220 patients recording their need for a blood transfusion, and the speed and completeness of their recovery.

Who can participate?
Adult patients receiving first-time, non-emergency, isolated aortic valve replacement (AVR) surgery will be invited to participate.

What does the study involve?
Patients who consent will be randomly allocated to receive their AVR via manubrium-limited ministernotomy or via conventional sternotomy. Patients will be unaware of the type of sternotomy received until two days following their operation. Patients will be followed for 3 months following their surgery to find out about any blood and blood product transfusions given following their surgery, quality of life and surgical success.

What are the possible benefits and risks of participating?
This research does not carry any additional risk compared to surgery performed as part of usual care. Receiving a blood or blood product transfusion also carries some risks. Receiving blood and blood products is part of usual care and therefore this research does not carry any additional risk.

Where is the study run from?
The study will take place at South Tees Hospitals NHS Foundation Trust, UK. The study will run in collaboration with Durham Clinical Trials Unit, Durham University, UK.

When is the study starting and how long is it expected to run for?
The study is due to begin recruiting in early 2014, and complete in early 2017

Who is funding the study?
The National Institute for Health Research (NIHR) (UK)

Who is the main contact?
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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
Funder number: PB-PG-1112-29035

Study information

Scientific Title

Manubrium-limited ministernotomy versus conventional sternotomy for Aortic Valve Replacement: a randomIsed Controlled trial (MAVRIC)

Acronym
MAVRIC

Study objectives
This randomised controlled trial will investigate whether a manubrium-limited sternotomy (intervention) reduces the need for red blood cell transfusion compared to a conventional sternotomy (control) in patients undergoing aortic valve replacement.

The null hypothesis is that there will be no difference in the proportion of patients receiving a red blood cell transfusion between the intervention and control groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - Newcastle & North Tyneside 1, 14/01/2014, ref: 14/NE/0005

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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
Manubrium-limited ministernotomy, conventional sternotomy, aortic valve replacement (AVR), red blood cell transfusion

Interventions
Patients will be randomised to receive Aortic Valve Replacement via Manubrium-Limited Ministernotomy (intervention arm) or Aortic Valve Replacement via Conventional Sternotomy (control arm).
1. Manubrium-limited ministernotomy (intervention arm) involves a midline incision in which the

manubrium is divided from the sternal notch to just below the manubrio-sternal junction.
2. Conventional sternotomy (control arm) involves a midline incision from the sternal notch to the xiphisternum.

All operations within the trial will be performed using systemic normothermia with appropriate cardiopulmonary bypass and myocardial protection. Patients will receive a mechanical, biological or sutureless valve. All pre- and post-operative care and procedures for both groups will be according to agreed unit practice. Patients will be in the study from consent until 12 weeks following their Aortic Valve Replacement surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
The proportion of patients who receive a red blood cell transfusion post-operatively within 7 days of AVR surgery

Secondary outcome measures
1. The proportion of patients who receive a red blood cell transfusion during the intra-operative period, post-operative period (from admission to CICU to 7 days)
2. The number of red blood cell transfusion units per patient within the 7 days following AVR surgery
3. The proportion of patients receiving platelet transfusion or receiving fresh frozen plasma transfusion within the 7 days following AVR surgery
4. The total number of patients receiving any blood products and the number of units transfused within the 7 days following AVR surgery and during the entire hospital stay
5. The average and range of postoperative blood loss within 6 and 12 hours after surgery
6. Re-operation rates following the end of index surgery
7. Quality of life EuroQol (EQ-5D-3L, EQ-VAS) measured at baseline, day 2, 6 weeks and 12 weeks
8. The average day and range of days upon which patients are deemed fit for discharge from hospital
9. Health care utilisation to 12 weeks post-surgery
10. Cost and cost effectiveness
11. Adverse event profiles related to study procedures for each arm

Overall study start date
01/02/2014

Completion date
31/01/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or older at the time of consent
2. Requiring first-time, non-emergency, isolated aortic valve replacement surgery
3. Able and willing to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
220 patients

Total final enrolment
270

Key exclusion criteria
1. Requiring concomitant cardiac procedure(s)
2. Haemoglobin level < 90g/L
3. Pregnant
4. Are unable to stop currently prescribed treatment affecting clotting
5. A history of thrombophilia, thrombocytopenia or other haematological conditions that would affect participation in the trial
6. Infective endocarditis
7. Prevented from having red blood cells and blood products according to a system of beliefs

Date of first enrolment
01/02/2014

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BW

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust (UK)

Sponsor details
Research & Development Department
Academic Centre
The James Cook University Hospital
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - The Research for Patient Benefit Programme, Ref: PB-PG-1112-29035

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	28/01/2017		Yes	No

Results article	results	21/05/2019	31/03/2020	Yes	No
Results article	results	29/01/2021	01/02/2021	Yes	No
HRA research summary			28/06/2023	No	No