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Minimally invasive thoracoscopically-guided right minithoracotomy versus conventional sternotomy for mitral valve repair

Submission date
22/08/2016

Recruitment status
No longer recruiting

Registration date
12/09/2016

Overall study status
Completed

Last Edited
18/11/2025

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Heart surgery to repair one of the valves in the heart (the mitral valve) is commonly performed in the NHS. Patients needing this operation sometimes suffer symptoms of shortness of breath (especially when exercising), tiredness, and swollen ankles, caused by the valve becoming leaky (mitral regurgitation). Some patients suffer very few symptoms. These patients are quite often of working age so time away from their place of work can be difficult for a number of reasons. Steps need to be taken to make sure that the operations offered within the NHS are best for patients. To repair the valve, the operation usually involves cutting the breastbone completely (from the collar bone to the bottom of the breastbone); this is called a sternotomy. An operation has been developed which means that the valve can be repaired using a much smaller cut on the side of the chest; this operation is called a mini-thoracotomy. It is not known which operation is better for patients and for the NHS because there is no good research to show what effects two different types of surgery to access the heart and repair the valve have on patients. This study will compare the two operations in four hundred adult patients to see how well they recover and return to normal activities.

Who can take part?
Adult patients with degenerative mitral valve disease requiring isolated mitral valve repair surgery.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given a mini-thoracotomy. Those in group 2 are given a sternotomy. Patients are asked questions about their physical activities and quality of life before and at various times after the operation. Other important factors are also be checked to see how well patients recover, including how well their valve works up to twelve weeks and twelve months after surgery using a heart scan (called an echocardiogram). Patients are asked to wear a device that measures their activity for one week on seven occasions; the device looks like a wrist-watch and can be worn all day and all night. Any complications following a patient's operation is recorded from their medical records. Costs of care for each operation is also calculated by looking at medical records to see how often

patients are seen in hospital after their operation. Patients who take part attend hospital a few times in the first year, after this their progress is monitored by reviewing their medical notes. Patients are asked to confirm that they are happy that the researchers keep looking at their medical records, even after the trial is finished.

What are the possible benefits and risks to participants?
This research does not carry any additional risk compared to surgery performed as part of usual care.

Where is the study run from?
The study will include patients from NHS hospitals in England, including the South Tees Hospitals NHS Foundation Trust (lead centre and sponsor), King's College Hospital NHS Foundation Trust, Basildon and Thurrock University Hospitals NHS Foundation Trust, Blackpool Teaching Hospitals NHS Foundation Trust. 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?
January 2016 to May 2023

Who is funding the study?
National Institute of Health Research – Health Technology Assessment Programme (UK)

Who is the main contact?
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Scientific

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Additional identifiers

Central Portfolio Management System (CPMS)
31443

Study information

Scientific Title
Minimally invasive thoracoscopically-guided right minithoracotomy versus conventional sternotomy for mitral valve repair: a multicentre randomised controlled trial (UK Mini Mitral).

Study objectives
This randomised controlled trial will investigate whether the minimally invasive thoracoscopically-guided right minithoracotomy approach to mitral valve repair allows for an improved return of physical functioning and a return to usual activities when compared to conventional sternotomy at 12 weeks.

Additionally, the study will compare the cost-effectiveness of the two surgical approaches at 52 weeks.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Gwasanaeth Moeseg Ymchwil Research Ethics Service, 28/06/2016, ref: 16/WA/0156

Study design
Randomized; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Degenerative mitral valve disease

Interventions

Patients are randomised to one of two groups. Those in group 1 receive mitral valve repair surgery by thoracosopically-guided right minithoracotomy (intervention group). Those in group 2 receive mitral valve repair surgery via a median sternotomy (control group).

1. Intervention group:
Minimally invasive surgery is by thoracoscopically-guided right minithoracotomy. The patient is intubated with a single or double lumen endotracheal tube. Cardiopulmonary bypass is established by aortic or femoral artery cannulation and venous return is achieved from the venae cavae using a single bicaval cannula placed from the femoral vein or with an additional cannula in the superior venae cava. Transoesophageal echocardiography (TOE) confirms the optimum location of the venous and arterial cannulas. A 4-7 cm right antero-lateral mini-thoracotomy, is then used to enter the thorax through the third or fourth intercostal space. A soft tissue retractor with or without a small thoracic retractor is utilized to spread the ribs with minimal rib-spreading. The pericardium is opened 3-4 cm anterior and parallel to the phrenic nerve from the distal ascending aorta to the diaphragm. A video camera is inserted through a 5-10 mm port. Endoballoon occlusion or a transthoracic clamp achieves aortic occlusion. Cardiac arrest is achieved with single or repeated doses of cardioplegia. The mitral valve is approached through a paraseptal incision and a left atrial retractor is used to expose the mitral valve. Following the mitral valve procedure, the left atrium is closed, the heart de-aired and aortic occlusion removed. Cardiopulmonary bypass is then discontinued and the thoracotomy incision closed once haemostasis has been achieved.

2. Control group:
Conventional mitral valve surgery will be performed via a median sternotomy, in which the sternum is divided completely (from the collarbone to the bottom of the breastbone). The operation includes cardiopulmonary bypass established by siting cannulas in the right atrium and inferior venae cava and ascending aorta. The heart is stopped with cardioplegia and the mitral valve is approached via the left atrium. The valve is repaired and assessed intra-operatively by water testing. If the repair is deemed satisfactory, the atrium is closed, de-airing manoeuvres are performed, and the aortic cross clamp is removed to allow reperfusion of the heart. Cardiopulmonary bypass is then discontinued and once haemostasis is performed the sternum is closed.

Patients will be randomised in a 1:1 ratio, using a minimisation scheme that will account for baseline SF-36v2 physical functioning score and the presence or absence of Atrial Fibrillation.

Patients will be followed-up for a period of 52 weeks on each treatment arm.

Intervention Type
Other

Primary outcome(s)
The change in the SF-36v2 physical functioning scale at 12 weeks post-surgery.

The SF-36v2 is a generic multi-dimensional and validated instrument consisting of eight multi-item components representing physical function, social function, role limitation attributable to physical problems, role limitation attributable to emotional problems, mental health, energy, pain, general health perception.

Key secondary outcome(s))

1. Level and variability in physical activity: measured using one week of accelerometer measurements at 7 time points (baseline, and 6, 12, 18, 24, 38 and 52 weeks following index surgery)
2. Quality of sleep: measured using one week of accelerometer measurements at 7 time points (baseline, and 6, 12, 18, 24, 38 and 52 weeks following index surgery)
3. Surgical outcomes (including duration of operation, cardiopulmonary bypass times, anaesthetic regime, protocol adherence), measured using data collected at the time of index surgery
4. Costs, including intervention-specific estimates, of the two operations, measured using data collected at the time of index surgery
5. Mitral valve related events determined using HES, NICOR, and medical record data, measured using adverse event data collected for 52 weeks within the trial, and through requests to HSCIC and NICOR for event data
6. Left ventricular volumes and function, mitral regurgitation, right heart function, and pulmonary artery pressure, measured by Echocardiograms at baseline, post-operatively and at 52 weeks following index surgery
7. Survival Measured throughout the trial and using ONS data
8. Physical functioning using SF-36v2, measured using the SF-36v2 questionnaire administered at 7 time points (baseline, and 6, 12, 18, 24, 38 and 52 weeks following index surgery)
9. Quality of life using SF-36v2 and EQ-5D-5L, measured using the SF-36v2 and EQ-5D-5L questionnaires administered at 7 time points (baseline, and 6, 12, 18, 24, 38 and 52 weeks following index surgery)
10. Adverse Events and Serious Adverse Events, measured throughout the trial using a combination of patient reported events and data provided by HSCIC and NICOR
11. Health care utilisation, measured using patient reported health care utilisation questionnaires at 6, 12, 18, 24, 38 and 52 weeks following index surgery
12. Wound pain, measured using an 11 point VAS scale at 3 days, 6 weeks and 12 weeks following index surgery
13. NYHA class, measured using the standard NYHA classifications at baseline, 6 and 12 weeks following index surgery
14. Length of hospital stay, measured from routinely collected hospital data following index surgery
15. Medication usage, measured using patient reported medication usage at baseline, and at 6, 12 and 52 weeks following index surgery.
16. Re-operation, measured using routinely collected hospital data following index surgery
17. Conversion (minimally-invasive arm only), measured using routinely collected hospital data following index surgery
18. Red blood cell and blood product transfusions, measured using routinely collected hospital data following index surgery
19. Time on ICU, HDU and ward, measured using routinely collected hospital data following index surgery
20. Discharge destination, measured using routinely collected hospital data following index surgery
21. Duration of ventilation, measured using routinely collected hospital data following index surgery
22. Blood loss following surgery, measured using routinely collected hospital data following index surgery

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Adult (≥18 years old at consent) patients with degenerative mitral valve disease, requiring isolated MVr (patients requiring concomitant surgery for Atrial Fibrillation and/or Patent Foramen Ovale (PFO) closure will be included)
2. Written informed consent
3. Fit for cardiac surgery and cardiopulmonary bypass

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
330

Key exclusion criteria
1. Concomitant cardiac surgery other than AF ablation and PFO closure
2. Requiring mitral valve replacement
3. Acute infective endocarditis
4. Emergency or salvage surgery
5. Only conventional median sternotomy or only minimally invasive surgery indicated
6. Pregnant*
7. Currently participating in another interventional clinical trial
8. Four weeks or more as an inpatient prior to randomisation
9. Previous cardiac surgery

*Female patients between the ages of 18 and 50 will receive a pregnancy test at baseline

Date of first enrolment
22/08/2016

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The James Cook University Hospital (Lead Centre)
Marton Road
Middlesbrough
England
TS4 3BW

Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/06/2023	15/06/2023	Yes	No
Results article		18/11/2025	18/11/2025	Yes	No
Protocol article		14/04/2021	16/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Statistical Analysis Plan			04/10/2024	No	No