







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

Submission date 22/08/2016	Recruitment status No longer recruiting	 Retrospectively registered
		 Protocol added
Registration date 12/09/2016	Overall study status Completed	 SAP not yet added
		 Results added
Last Edited 15/06/2023	Condition category Circulatory System	 Raw data not yet added
		 Study completed

Plain English Summary

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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Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

31443

Study information

Scientific Title

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

Study hypothesis

This randomised controlled trial will investigate whether the minimally invasive thoroscopically-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

Randomised; Interventional; Design type: Treatment, Surgery

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

Condition

Degenerative mitral valve disease

Interventions

Patients are randomised to one of two groups. Those in group 1 receive mitral valve repair surgery by thoracoscopically-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 measure

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.

Secondary outcome measures

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

Overall study start date

01/01/2016

Overall study end date

31/05/2023

Eligibility

Participant 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

158 in each arm

Total final enrolment

330

Participant 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

Recruitment start date

22/08/2016

Recruitment end date

31/05/2021

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

The James Cook University Hospital (Lead Centre)

Marlon Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre

King's College Hospital

Denmark Hill
Denmark Hill
United Kingdom
SE5 9RS

Study participating centre

Blackpool Victoria Hospital

Whinney Heys Road
Blackpool
United Kingdom
FY3 8NR

Study participating centre

Basildon University Hospital

Nethermayne
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United Kingdom
SS16 5NL

Study participating centre

NHS Lothian

Waverley Gate
2-4 Waterloo Place
Edinburgh
United Kingdom
EH1 3EG

Study participating centre

Hammersmith Hospitals NHS Trust

Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre

Harefield Hospital NHS Trust

Harefield
United Kingdom
UB9 6JH

Study participating centre

University Hospitals Bristol and Weston NHS Foundation Trust

Trust Headquarters
Marlborough Street
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BS1 3NU

Study participating centre

University Hospitals Plymouth NHS Trust

Derriford Hospital
Derriford Road
Derriford

Plymouth
United Kingdom
PL6 8DH

Study participating centre
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool
United Kingdom
L14 3PE

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

Sponsor details
R&D Department
The James Cook University Hospital
Institute for Learning, Research and Innovation
Marton Road
Middlesbrough
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United Kingdom
TS4 3BW

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/02js17r36>

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

1. The protocol has been published on the NIHR HTA website at the start of the trial.
2. Following the trial patients that have been involved in the trial will be informed of the results in a letter sent to them; we will also explore other ways of reaching patients (for example using social media) as the trial develops and tailor our dissemination of trial findings to them accordingly.
3. Surgeons and cardiothoracic units around the country will be engaged directly to share the results and the expertise required to adopt the new technique, if indicated by trial findings. The results will be presented to appropriate meetings including: The Annual Meetings of the European Association of Cardiothoracic Surgery, Society for Cardiothoracic Surgeons in Great Britain and Ireland Conference, and the Society of Thoracic Surgeons to maximise the exposure of findings to cardiac surgeons treating patients requiring mitral valve repair.
4. The researchers aim to publish the results in high impact journals, such as: Circulation, Journal of Thoracic and Cardiovascular Surgery, Annals of Thoracic Surgery and The European Journal of Cardiothoracic Surgery.

Intention to publish date

31/12/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		14/04/2021	16/04/2021	Yes	No
Results article		13/06/2023	15/06/2023	Yes	No
HRA research summary			28/06/2023	No	No