

A pragmatic, prospective, randomised controlled trial comparing upper ministernotomy to full median sternotomy as a surgical approach for aortic valve replacement

Submission date 24/06/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/06/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 01/10/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

7766

Study information

Scientific Title

A pragmatic, prospective, randomised controlled trial comparing upper ministernotomy to full median sternotomy as a surgical approach for aortic valve replacement

Acronym

MiniStern Trial

Study objectives

MiniStern is a pragmatic, prospective randomised controlled trial comparing upper mini-sternotomy to full median sternotomy as a surgical approach to first time isolated aortic valve replacement (AVR).

Ethics approval required

Old ethics approval format

Ethics approval(s)

MREC approved (ref: 09/H0301/58)

Study design

Single-centre randomised interventional treatment trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Cardiovascular, Generic Health Relevance and Cross Cutting Themes; Subtopic: Cardiovascular (all Subtopics), Generic Health Relevance (all Subtopics); Disease: Cardiovascular, Surgery

Interventions

Comparing upper mini-sternotomy to full median sternotomy as a surgical approach to first time isolated aortic valve replacement (AVR).

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Total length of stay in hospital for the index AVR operation measured in days

Secondary outcome measures

1. Fitness for discharge
2. Health related quality of life and patient satisfaction at baseline, 6 weeks, 6 months and 12 months using the 36-item short form health survey (SF-36) and Coronary Revascularization Outcome Questionnaire - Coronary Artery Bypass Graft (CROQ-CABG)
3. Heart function (LVEF) by echocardiography at baseline, day of discharge and 6 months post surgery
4. Procedure time: total theatre time, cross clamp time, cardiopulmonary bypass time, blood loss, blood transfusion
5. Respiratory function (forced expiratory volume in one second [FEV1]) by hand held spirometry at baseline, day 4, day of discharge, 6 weeks and 6 months

Overall study start date

30/11/2009

Completion date

01/09/2012

Eligibility

Key inclusion criteria

1. Aged greater than 18 years at the time of surgery, either sex
2. Elective, first time, isolated aortic valve replacement (AVR)

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 240

Total final enrolment

222

Key exclusion criteria

1. Documented poor left ventricular (LV) function or left ventricular ejection fraction (LVEF) 30%
2. Documented chest wall deformities

3. Documented severe emphysema or chronic obstructive pulmonary disease (COPD)
4. Current body mass index (BMI) greater than 35 kg/m²
5. Concomitant cardiac surgery
6. Redo surgery
7. Median sternotomy indicated

Date of first enrolment

30/11/2009

Date of final enrolment

01/09/2012

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Papworth Hospital NHS Foundation Trust

Cambridge

United Kingdom

CB23 3RE

Sponsor information

Organisation

Papworth Hospital NHS Foundation Trust (UK)

Sponsor details

Papworth Everard

Cambridge

England

United Kingdom

CB3 8RE

Sponsor type

Hospital/treatment centre

Website

<http://www.papworthhospital.nhs.uk/index.php>

ROR

<https://ror.org/01qbebb31>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Central Commissioning Facility (CCF)

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?
Results article	results	01/12/2018	01/10/2019	Yes	No
HRA research summary			28/06/2023	No	No