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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

Registration date
24/06/2010

Overall study status
Completed

Last Edited
01/10/2019

Condition category
Surgery

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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/m^2
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