ISRCTN56511757 https://doi.org/10.1186/ISRCTN56511757

Prospective randomised trial of stented versus stentless bioprosthesis for aortic valve replacement (AVR)

Submission date
16/05/2005

Recruitment status
No longer recruiting

Registration date
08/07/2005

Overall study status
Completed

Last Edited
04/10/2007

Condition category
Circulatory System

[_] 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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
P00715

Study information

Scientific Title

Study objectives
To find out which prosthetic valves represent the better option for patients requiring AVR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Aortic valve replacement

Interventions
Prima Plus (Edwards Lifesciences) stentless bioprosthesis or the Carpentier-Edwards Perimount stented bioprosthesis (Edwards Lifesciences).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Post-operative pressure gradient across the prosthetic valve and effective valve orifice area.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/03/2001

Completion date
05/07/2005

Eligibility

Key inclusion criteria
Inclusion criteria:
1. Patients who require elective AVR with a tissue valve for symptomatic aortic valve stenosis (peak valve gradient equal to or greater than 50 mmHg as measured by echocardiography), with or without concomitant artery bypass grafting
2. Patients = 65 years of age at the time of surgery

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
240

Key exclusion criteria
1. Patients who are already enrolled in another major cardiovascular trial
2. AVR performed primarily for aortic valve regurgitation
3. Active aortic valve infection
4. Active malignant disease
5. Renal failure requiring dialysis
6. Any previous cardiac surgery
7. The need for additional cardiac procedures other than coronary artery bypass grafting
8. Emergency operations
9. Patients unable to give informed consent

Date of first enrolment
01/03/2001

Date of final enrolment
05/07/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Surgical Unit
Papworth Everard
United Kingdom
CB3 8RE

Sponsor information

Organisation
Papworth Hospital NHS Trust (UK)

Sponsor details
Surgical Unit
Papworth Everard
England
United Kingdom
CB3 8RE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Industry

Funder Name
Edwards LifeSciences Ltd (UK) - Industrial grant

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	01/06/2007		Yes	No