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

Submission date 16/05/2005	Recruitment status No longer recruiting	Prospect Protocol
Registration date 08/07/2005	Overall study status Completed	[_] Statistica [X] Results
Last Edited 04/10/2007	Condition category Circulatory System	[_] Individua

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

Contact name Mr Steven Tsui

Contact details

Surgical Unit Papworth Hospital NHS Trust Papworth Everard United Kingdom **CB3 8RE**

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers P00715

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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:

 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
 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?
<u>Results article</u>	Results	01/06/2007		Yes	No