

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

Submission date 16/05/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 08/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/10/2007	Condition category Circulatory System	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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**

United Kingdom

England

Study participating centre**Surgical Unit**

Papworth Everard

United Kingdom

CB3 8RE

Sponsor information**Organisation**

Papworth Hospital NHS Trust (UK)

ROR

https://ror.org/01qbebb31

Funder(s)

Funder type

Industry

Funder Name

Edwards LifeSciences Ltd (UK) - Industrial grant

Results and Publications

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