

Prospective comparison of two carbon valve prostheses

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/10/2009	Condition category Surgery	☐ 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
N0264073738

Study information

Scientific Title

Study objectives

Comparison of long-term clinical outcome with two bileaflet carbon prostheses.

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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Surgery: Mechanical heart valve replacement

Interventions

Randomised prospective trial.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

1. Death
2. Thromboembolic events
3. Bleeding
4. Valve dysfunction.

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/02/2005

Eligibility**Key inclusion criteria**

Patients undergoing mechanical heart valve replacement.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/07/1993

Date of final enrolment

01/02/2005

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

c/o Research and Development Office

Bristol

United Kingdom

BS2 8HW

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)**Funder type**

Government

Funder Name

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	01/01/2002		Yes	No
Results article	results	01/03/2007		Yes	No