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Prospective comparison of two carbon valve prostheses

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 05/10/2009	**Condition category** Surgery	

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

Primary study design
Interventional

Study design
Randomised controlled trial

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

United Bristol Healthcare NHS Trust (UK)

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