Prospective comparison of two carbon valve prostheses

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/1993

Completion date

01/02/2005

Eligibility

Key inclusion criteria

Patients undergoing mechanical heart valve replacement.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

485

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

England

United Kingdom

Study participating centre c/o Research and Development Office

Bristol United Kingdom BS2 8HW

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

Sponsor type

Government

Website

http://www.doh.gov.uk

Funder(s)

Funder type

Government

Funder Name

United Bristol Healthcare NHS Trust (UK)

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	01/01/2002		Yes	No

Results article results 01/03/2007 Yes No