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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

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