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Comparison of outcomes following aortic valve replacement with two different types of valve substitutes

Submission date	Recruitment status	[_] Prospectively registered
17/02/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
25/03/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/11/2023	Circulatory System	

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
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
N/A

Study information

Scientific Title
A prospective randomised trial comparing autograft versus homograft aortic root replacement

Study objectives
Homografts and autografts have been used for many years with good clinical and haemodynamic results. In contrast to homografts, autografts are the only valve substitutes which ensure long-term viability of the aortic valve. We believe that this translates into clinically relevant endpoints following aortic root replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hillingdon Health Authority approved on the 12th January 1994

Study design
Single-centre prospective randomized comparison trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Aortic valve disease

Interventions
Two interventions will be compared:
1. Homograft aortic root replacement with coronary reimplantation
2. Autograft aortic root replacement with coronary reimplantation and replacement of the pulmonary root with a homograft

The operations will be carried out by a single surgeon (Sir Magdi Yacoub). The surgical techniques are well established and have been previously published.

Patients will be followed at 1 month, 6 months, 1 year and yearly thereafter with outpatient clinic appointments and echocardiographic evaluation. In patients with normal and stable echocardiographic results and no functional limitation, the follow-up will be extended to every 2 years.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Survival at 10 years

Secondary outcome measures
1. Incidence of the need for reoperation
2. Quality of life (QOL): assessed using the 36-item Short Form health survey (SF-36) quality of life standardised questionnaire, which will be sent by mail with a return envelope to all patients
3. Incidence of valve-related complications: endocarditis, major bleeding, thrombosis or thromboembolism
4. Specific echocardiographic parameters:
4.1. Progression of transaortic pressure gradient
4.2. Progression in the degree of aortic regurgitation and incidence of aortic regurgitation grade 3+ and 4+
4.3. Changes in aortic root diameter measured at the sinuses of Valsalva and incidence of aortic root dilatation greater than 45 mm
4.4. Changes in left ventricular end-diastolic and end-systolic diameters
4.5. Changes in ejection fraction
4.6. Progression of transpulmonary gradient through the homograft in the autograft group

Overall study start date
15/05/1994

Completion date
15/11/2001

Eligibility

Key inclusion criteria
1. Patients with symptomatic aortic valve disease requiring aortic valve replacement
2. Patients with concomitant aortic root dilatation and/or ascending aortic dilatation and aortic valve dysfunction requiring surgery
3. Patients with bicuspid aortic valve disease requiring aortic valve replacement
4. Patients with aortic valve endocarditis
5. Patients who have undergone previous cardiac surgery
6. Aged less than 69 years, either sex
7. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
5 Years

Upper age limit
69 Years

Sex
Both

Target number of participants
216

Total final enrolment
228

Key exclusion criteria
1. Marfan syndrome
2. Reither's syndrome
3. Rheumatoid arthritis
4. Aged less than 5 years or greater than 69 years
5. Inability to consent
6. Other known disease potentially shortening life expectancy to less than 15 years
7. When completeness of follow-up is judged unlikely by the investigators

Date of first enrolment
15/05/1994

Date of final enrolment
15/11/2001

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Harefield Heart Science Centre
Harefield
United Kingdom
UB9 6JH

Sponsor information

Organisation
Royal Brompton and Harefield NHS Foundation Trust (UK)

Sponsor details
Harefield Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.rbht.nhs.uk/

ROR
https://ror.org/02218z997

Funder(s)

Funder type
Charity

Funder Name
The Magdi Yacoub Institute (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		14/08/2010		Yes	No
Other publications	Post hoc analysis	08/11/2023	09/11/2023	Yes	No