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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
17/02/2010		☐ 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

Contact name

Prof Magdi Yacoub

Contact details

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Additional identifiers

EudraCT/CTIS numberNil 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 Hill End Road Harefield England United Kingdom UB9 6JH

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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