

Anticoagulation following tissue aortic valve replacement

Submission date 27/03/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 10/04/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 19/10/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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
06/Q0803/36

Study information

Scientific Title

Anticoagulation following tissue aortic valve replacement

Acronym

AFTAV

Study objectives

Null hypothesis:

There is no difference in rates of neurological events following aortic valve replacement (AVR) with reference to oral anticoagulation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

No provided at time of registration

Study design

Prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet**Health condition(s) or problem(s) studied**

Aortic valve disease

Interventions

Three groups: warfarin therapy for 90 days, aspirin therapy for 90 days, control group (no medication)

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Neurological events
2. Stroke

Secondary outcome measures

Thrombus formation

Overall study start date

01/05/2006

Completion date

01/05/2007

Eligibility

Key inclusion criteria

Patients undergoing tissue aortic valve replacement

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

400

Key exclusion criteria

1. Patients who require aspirin or warfarin therapy on established medical grounds
2. Patients unable to take warfarin or aspirin

Date of first enrolment

01/05/2006

Date of final enrolment

01/05/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

St George's Healthcare NHS Trust

London

United Kingdom

SW17 0QT

Sponsor information

Organisation

St George's Healthcare NHS Trust (UK)

Sponsor details

Blackshaw Road
Tooting
London
England
United Kingdom
SW17 0QT

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/039zedc16>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

St George's Heart Science Fund

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