

# Haemodynamic performance and clinical outcome following aortic valve replacement

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/05/2018	<b>Condition category</b> Surgery	<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**  
N0123138101

# Study information

## Scientific Title

Haemodynamic performance and clinical outcome following aortic valve replacement

## Study objectives

To investigate the influence of the surgical correction of aortic valve disease and of the type of prostheses used on:

1. The rate and extent of regression of myocardial hypertrophy
2. The recovery of normal cardiac function
3. The clinical outcome

## 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

Cardiovascular surgery

## Interventions

Randomised controlled trial

## Intervention Type

Procedure/Surgery

## Phase

Not Specified

## Primary outcome measure

Haemodynamic performance and clinical outcome following aortic valve replacement

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/06/2001

**Completion date**

31/05/2003

## Eligibility

**Key inclusion criteria**

Aortic valve replacement

**Participant type(s)**

Patient

**Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

Not provided at time of registration

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/06/2001

**Date of final enrolment**

31/05/2003

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

University Hospitals of Leicester

Leicester

United Kingdom

LE1 4PW

# Sponsor information

## Organisation

Department of Health

## Sponsor details

Richmond House  
79 Whitehall  
London  
United Kingdom  
SW1A 2NL

## Sponsor type

Government

## Website

<http://www.dh.gov.uk/Home/fs/en>

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

University Hospitals of Leicester 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