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# The United Kingdom Transcatheter Aortic Valve Implantation (UK TAVI) Trial. A multi-centre randomised controlled trial to assess the clinical effectiveness and cost utility of TAVI, compared with conventional surgical aortic valve replacement (AVR), in patients with severe symptomatic aortic stenosis at intermediate or high operative risk

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| **Submission date**<br>12/06/2013 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>12/06/2013 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited**<br>18/05/2022 | **Condition category**<br>Circulatory System | [_] Individual participant data |

## Plain English summary of protocol

Background and study aims

Aortic stenosis is a narrowing of the valve through which blood flows as it leaves the heart, and affects 13% of people over the age of 70 years. It is usually due to age-related degeneration. If the narrowing becomes severe, chest pain, breathlessness, fluid retention and fainting are common, and the outlook is poor with a high risk of death within 2-3 years. The only effective conventional treatment is surgical replacement of the valve, which involves open chest surgery and temporarily stopping the heart, with use of a heart-lung machine. Surgical results are generally excellent but the elderly often have other medical problems that may result in an increased risk of death and complications. Transcatheter Aortic Valve Implantation (TAVI) is a recently developed technique to implant an artificial aortic valve without major surgery, using a catheter to deliver the valve to the heart through the arteries, which are usually accessed by puncturing the skin in the groin. In some cases, the valve is delivered directly through a small incision in the chest wall. The proposed study will compare TAVI with conventional surgery.

Who can participate?

Patients aged 70 years or over for whom either treatment is an option but in whom the risks of surgery are considered by an expert local medical team to be intermediate or high.

What does the study involve?

Each patient who consents to take part will be randomly assigned to receive either TAVI or

surgery. Outcomes in each group will be compared to see whether TAVI offers advantages in the short term and whether the long-term results, over 5 years, are as good as surgery. The cost implications for the NHS will be assessed to see if TAVI offers value for money.

What are the possible benefits and risks of participating?
The results of the study will inform NHS policy for the use of TAVI and guide treatment decisions for future patients.

Where is the study run from?
University of Leicester (UK)

When is the study starting and how long is it expected to run for?
August 2013 to October 2022

Who is funding the study?
NIHR Health Technology Assessment (UK)

Who is the main contact?
Dr William D. Toff
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### Study website
http://www.uktavi.org

# Contact information

### Type(s)
Scientific

### Contact name
Dr William D Toff

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
14550; HTA 09/55/63

# Study information

### Scientific Title
The United Kingdom Transcatheter Aortic Valve Implantation (UK TAVI) Trial. A multi-centre randomised controlled trial to assess the clinical effectiveness and cost utility of TAVI, compared with conventional surgical aortic valve replacement (AVR), in patients with severe symptomatic aortic stenosis at intermediate or high operative risk

### Acronym
UK TAVI

### Study objectives
Aortic stenosis, narrowing of the valve through which blood flows as it leaves the heart, affects 1-3% of people over the age of 70 years. It is usually due to age-related degeneration. If the narrowing becomes severe, chest pain, breathlessness, fluid retention and fainting are common, and the outlook is poor with a high risk of death within 2-3 years.

The only effective conventional treatment is surgical replacement of the valve, which involves open chest surgery and temporarily stopping the heart, with use of a heart-lung machine. Surgical results are generally excellent but the elderly often have other medical problems that may result in an increased risk of death and complications.

Transcatheter Aortic Valve Implantation (TAVI) is a recently developed technique to implant an artificial aortic valve without major surgery, using a catheter to deliver the valve to the heart through the arteries, which are usually accessed by puncturing the skin in the groin. In some cases, the valve is delivered directly through a small incision in the chest wall.

The proposed study will compare TAVI with conventional surgery in a group of patients, aged 70 years or over, for whom either treatment is an option but in whom the risks of surgery are considered by an expert local medical team to be intermediate or high. Each patient who consents to take part will be randomly assigned to receive either TAVI or surgery. Outcomes in each group will be compared to see whether TAVI offers advantages in the short-term and whether the long-term results, over 5 years, are as good as surgery.

The cost implications for the NHS will be assessed to see if TAVI offers value for money. The results of the study will inform NHS policy for the use of TAVI and guide treatment decisions for individual patients.

The primary study hypothesis is that in patients with severe symptomatic aortic stenosis who are at intermediate or high operative risk, Transcatheter Aortic Valve Implantation (TAVI) is non-inferior to surgical aortic valve replacement in respect of death from any cause at one year.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)

First Medical Research Ethics Committee (MREC), 10/04/2013, 13/LO/0451

## Study design
Randomised; Interventional; Design type: Treatment

## 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
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiac Surgery

## Interventions
1. Surgical AVR, Surgical Aortic Valve Implantation
2. TAVI, Transcatheter Aortic Valve Implantation
Follow Up Length: 60 month(s); Study Entry: Single Randomisation only

## Intervention Type
Other

## Phase
Not Applicable

## Primary outcome measure
All-cause mortality; Timepoint(s): One year

## Secondary outcome measures
1. All-cause mortality at 30 days, 2, 3, 4 and 5 years
2. Cardiovascular mortality at 30 days and annually to 5 years
3. Quality-adjusted survival at 3 months and annually to 5 years
4. Stroke at 30 days and annually to 5 years
5. Re-intervention at 30 days and annually to 5 years
6. Death from any cause or stroke at 30 days and annually to 5 years
7. Death from any cause or disabling stroke at 30 days and annually to 5 years
8. Death from any cause, stroke or re-intervention at 30 days and annually to 5 years
9. Quality of life (Minnesota Living With Heart Failure Questionnaire at 6 weeks and 1 year; EQ-5D-5L at 2 weeks, 6 weeks, 3 months, 6 months and annually to 5 years)
10. Symptoms and functional capacity (CCS scale and NYHA class at 6 weeks, 3 months, 6 months and annually to 5 years; Nottingham EADL and 6-min walk at 6 weeks and 1 year)

11. Cognitive function (Mini-Mental-State-Index at 6 weeks and 1 year)
12. Procedural success and in-hospital complications
13. Duration of post-procedural hospital stay
14. Vascular complications at 30 days and 1 year
15. Major bleeding at 30 days and 1 year
16. Infective endocarditis at 30 days and annually to 5 years
17. Myocardial infarction at 30 days and annually to 5 years
18. Conduction disturbance requiring permanent cardiac pacing pre-discharge and at 1 year
19. Renal replacement therapy at 30 days and 1 year
20. Echocardiographic measures (left ventricular ejection fraction, mass, dimensions and volumes; aortic regurgitation; aortic valve gradient and area, at 6 weeks and 1 year)
21. Costs, cost-utility and incremental cost-effectiveness ratio at 1 year, 5 years and estimated over lifetime using an extrapolation model

### Overall study start date
01/08/2013

### Completion date
31/10/2022

## Eligibility

### Key inclusion criteria
1. Severe symptomatic aortic stenosis referred for intervention
2. Age ≥80 years or age ≥70 years with intermediate or high operative risk from conventional AVR, as determined by the MDT
3. Both conventional AVR and TAVI deemed to be acceptable treatment options;
4. Participant able and willing to give written informed consent
5. Participant able (in the investigators opinion) and willing to comply with all study requirements
Target gender: male and female; lower age limit: 70 years

### Participant type(s)
Patient

### Age group
Senior

### Sex
Both

### Target number of participants
Planned Sample Size: 808; UK Sample Size: 808

### Total final enrolment
913

### Key exclusion criteria
1. Intervention deemed inappropriate due to co-morbidity or frailty
2. Life expectancy less than one year due to co-morbidity
3. Previous AVR or TAVI

4. Technically unsuitable for either AVR or TAVI
5. Concomitant coronary artery disease requiring revascularisation for which only surgery is considered appropriate
6. Predominant aortic regurgitation
7. Severe mitral regurgitation or likely need for concomitant surgery or cardiac intervention other than planned coronary artery surgery or percutaneous coronary intervention as part of the treatment strategy

### Date of first enrolment
01/08/2013

### Date of final enrolment
31/03/2018

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**University of Leicester**
Leicester
United Kingdom
LE3 9QP

## Sponsor information

### Organisation
University of Leicester (UK)

### Sponsor details
Research Governance Office
University of Leicester
Academic Department
Leicester General Hospital
Gwendolen Road
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LE5 4PW

### Sponsor type
University/education

**Website**
http://www.le.ac.uk/

**ROR**
https://ror.org/04h699437

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme; Grant Codes: 09/55/63

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**
Not provided at time of registration

**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 | | 17/05/2022 | 18/05/2022 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |