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Aortic valve replacement in high risk patients: conventional surgery compared with catheter-based techniques

Submission date 22/04/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 26/05/2009	**Overall study status** Completed	
Last Edited 10/08/2017	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title

Randomised trial of transcutaneous versus surgical aortic valve replacement

Acronym
TAVI AVR

Study objectives
1. To assess efficacy and safety of the trans-catheter aortic valve implantation (TAVI)
2. To compare efficacy and safety of TAVI with surgical AVR (Cohort A)
3. To compare safety and efficacy of TAVI with medical therapy (Cohort B)
4. To keep a registry of all patients undergoing TAVI

To propose TAVI, incremental clinical benefits in a well-defined cohort of patients with the use of rigorous clinical trials need to be demonstrated. That is, these new therapy approaches must have substantive clinical value and cannot simply be the fashionable extrapolation of previous catheter-based treatments for coronary artery and other vascular diseases. To date, TAVI has been restricted to patients at high risk or with contraindication for surgery. The main outcome measure reported has been mortality at 30 days and, in some cases, morbidity. We do not know six month outcome in TAVI, as reported in the literature. Furthermore, quality of life and survival measured beyond three months is scarcely reported. With the economic demand of an ageing population on healthcare, there are no economic analysis and cost-effectiveness of TAVI alone or in comparison with surgical AVR. Although there is enormous enthusiasm for TAVI, it must be emphasised that this technology is in its infancy. It is very important that the patients' needs and quality of life are considered and that clinicians are not drawn into doing the procedure simply because it is a novelty. However, one can legitimately raise the question whether TAVI in a morbid, elderly patient cohort should be held to the same high standards as surgical therapies performed in younger and healthier patients.
Assuming that a standard for comparison and analysis of results should be whatever therapy a given patient would usually receive, some transcutaneous devices may be best suited for comparison with surgical valve replacements, whereas others may require comparisons with medical therapy. For example, in patients with heart failure and comorbidities, where surgery is totally contraindicated, TAVI should be compared to medical therapy.
European and American Heart Association guidelines and NICE recommend that each patient should be considered in a multidisciplinary meeting consisting of an interventional cardiologist, cardiac surgeon and cardiac anaesthetist. To address whether patients would benefit from only medical therapy, a non-interventional cardiologist should also be present. In view of the current status of TAVI, lack of consistency in selection of patients, reporting of outcomes, the European and American guidelines recommend a randomised study as outlined above and also the need to keep an accurate registry.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wandsworth Research Ethics Committee, St George's University of London, approval pending as of 22/04/2009

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe aortic valve stenosis

Interventions
Arm 1: Transcutaneous aortic valve implantation (n = 219)
Arm 2: Aortic valve replacement (n = 219)
Arm 3: Best medical therapy (n = 219)

Intervention Type
Procedure/Surgery

Primary outcome(s)
Death within the first year

Key secondary outcome(s))
The following will be assessed at 1, 3, 6 and 12 months for the first year, then 6-monthly until the end of 3rd year:
1. Evidence of prosthetic valve dysfunction
2. Postoperative bleeding
3. Freedom from major adverse cardiac and cerebrovascular complications
4. Heart block and need for pacemaker implantation
5. Conversion from TAVI, emergency valve surgery
6. Length of hospital stay and discharge to rehabilitation centre or home
7. Length of hospital stay
8. Improved quality of life, assessee by SF-36® Health Survey and Six-Minute Walk test

Completion date
31/08/2012

Eligibility

Key inclusion criteria
1. After a multidisciplinary meeting, patients (both males ane females) with expected mortality >15% (Euroscore) and/or >10% (Society of Thoracic Surgeons Mortality Risk [STS] score)
2. Severe aortic stenosis, confirmed by trans-thoracic echocardiography using a combination of measurements of valve area and flow dependent indices (mean gradient >50 mmHg). Low dose dobutamine echocardiography is useful to differentiate between severe and the rare 'pseudo-severe' aortic stenosis in patients with low left ventricular ejection fraction and low gradient.
3. Severe aortic stenosis, +/- one vessel coronary artery disease amenable to percutaneous intervention
4. Age >70 (if age <70, need to have other significant comorbidities)
5. Symptomatic patients with New York Heart Association (NYHA) grade >II
6. Patients who are able to give consent
7. If it is thought that risks of mortality and morbidity with surgery outweigh the benefits, the patients will be randomised into cohort B

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Aortic regurgitation
2. Patient preference - TAVI is not recommended for patients who simply refuse surgery on the basis of personal preference
3. Aortic annulus <18 or >25 mm for balloon expandable and <20 or >27 mm for self-expandable devices
4. Bicuspid aortic valve
5. Present of asymmetric heavy valvular calcification
6. Aortic root dimensions >4.5 cms
7. Presence of apical left ventricular thrombus
8. Evidence of acute myocardial infarction <30 days
9. Hypertrophic cardiomyopathy
10. Life expectancy <1 year due to non-cardiac causes

Specific contraindications for transfemoral approach:
1. Iliac arteries with severe calcification tortuousity and small diameter (6-9 mm), previous aorto-femoral bypass
2. Severe angulation of aorta and atheroma of the outcome and coaptation, aneurysm of the abdominal aorta with mural thrombus
3. Presence of bulky atherosclerosis of the ascending aorta and arch

Specific contraindications for the transapical approach:
1. Previous surgery of the left ventricle using a patch such as the Dor procedure
2. Calcified pericardium
3. Severe respiratory insufficiency

Date of first enrolment
01/09/2009

Date of final enrolment
31/08/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's Healthcare NHS Trust
London
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Sponsor information

Organisation
St George's Healthcare NHS Trust (UK)

ROR
https://ror.org/039zedc16

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - decision pending as of 22/04/2009.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration