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Cost outcomes study of transcatheter aortic valve implantation with contemporary valves

Submission date
22/05/2026

Recruitment status
Recruiting

Registration date
24/06/2026

Overall study status
Ongoing

Last Edited
24/06/2026

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The transcatheter aortic valve implantation (TAVI) procedure has been in clinical practice for several years for patients who suffer from significant symptoms due to a narrowed aortic valve and who cannot undergo an open-heart operation due to various reasons, for example, if they are elderly and are at high risk of complications after major operations. In these patients, the TAVI procedure is a good alternative and has shown to improve quality of life and prognosis. There are several TAVI valves available; however, only three of them have been tested in randomised clinical trials. There is a continuous and significant increase in the number of patients undergoing TAVI procedures every year. As these valves are expensive, this has resulted in a significant burden on the NHS budget in treating these patients. The purpose of this study is to assess if, following implantation, there is any difference between the three contemporary aortic transcatheter heart valves (THVs), i.e., the Meril Myval THV Series, the Edwards Sapien THV Series and the Medtronic Evolut THV Series, in health-related quality of life and cost-effectiveness of the TAVI procedure. This trial will provide valuable data which can be used to develop future guidance about how to manage these patients with aortic valve narrowing in a cost-effective manner.

Who can participate?
Patients aged 18 years and over who have been scheduled to undergo TAVI as part of normal clinical care.

What does the study involve?
Once a participant has agreed to participate and signed the consent form, the research team will collect existing information that their clinical care team have recorded about their physical health, medications and tests, including an ultrasound scan of the heart and a CT scan. The research team will complete a quality-of-life assessment with the patient using some questionnaires, which takes around 15 minutes.
They will be randomly allocated to have TAVI with one of the three valves (Evolut, Sapien or Myval THV series), which are all currently being used in routine clinical practice in the NHS. All these valves are backed by robust clinical effectiveness data in large trials. A computer will select the valve they receive at random.
The TAVI procedure will be done by the clinical team as per standard clinical care. The research

team will collect the procedural information.
Around 30 to 45 days after the TAVI procedure, the research team will complete the same quality-of-life assessment again, either during a face-to-face clinic appointment or over the telephone. The results of this will be compared with the assessment before the TAVI procedure. If the participant attends a face-to-face clinic appointment for this assessment, your travel expenses will be provided by the research team. This visit would be in addition to any follow up that the local healthcare team may decide to do as part of their routine clinical care post-TAVI. The local care team would write to the participant's GP (with permission) to inform them that they are taking part in this study.

What are the possible benefits and risks of participating?
Although there are no direct benefits for taking part in this study (as we are only collecting information from the planned procedure). It is hoped that this research will benefit future patients and health services.
Nevertheless, participants will have an additional review at 30 (+15) days, either in person or via telephone (as per preference); participants will be asked to complete a questionnaire to assess quality of life and compare it with the assessment before the TAVI procedure. The research team can then inform the clinical care team if any adverse event is identified.

Where is the study run from?
Northern General Hospital (UK)

When is the study starting and how long is it expected to run for? 1 year and 6 months.
May 2026 to November 2027

Who is funding the study?
Meril Lifesciences Pvt. Ltd (India)

Who is the main contact?
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Additional identifiers

Integrated Research Application System (IRAS)
363673

Central Portfolio Management System (CPMS)
71884

Study information

Scientific Title
Cost Outcomes Study of Transcatheter Aortic Valve Implantation with contemporary valves: the COS-TAVI Trial

Acronym
COS-TAVI

Study objectives
The primary objective is to compare the cost effectiveness of three main TAVI devices used in contemporary practice.

The principal question that will be addressed by this trial is whether there is any difference in health-related quality of
life and cost-effectiveness by implantation of one of the three TAVI devices.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 29/04/2026, North East - Newcastle & North Tyneside 2 Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; -; newcastlenorthtyneside2.rec@hra.nhs.uk), ref: 26/NE/0075

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Transcatheter aortic valve implantation (TAVI) procedure for patients who suffer from significant symptoms due to a narrowed aortic valve and who cannot undergo an open-heart operation

Interventions
All patients with severe symptomatic narrowing of the aortic valve, where the local clinical team decides to offer the TAVI procedure to them, will be screened to assess suitability for the trial. Patients who meet the inclusion and exclusion criteria and are willing to participate after reading the patient information sheet will be enrolled in this trial.

Patients will sign the study consent form. The research team will then collect baseline demographic and clinical data, including routine tests performed as work-up for TAVI. Participants will have their baseline quality of life assessment as part of the trial.

Participants would then be randomised to one of three study arms – the Myval THV series, the Sapien THV series or the Evolut THV series – and undergo the TAVI procedure as per the clinical guidelines and local study centre protocols. Participants will have standard post-TAVI care as per local guidelines and be discharged when the clinical team makes that decision. The research team will collect the details of the procedure, any adverse events/serious adverse events and the costs of the procedure and care.

The research team will review participants either face-to-face or in a telephone call at 30 (+15) days post-TAVI to assess quality of life and any adverse/serious adverse events. Participants would also be enquired about the number of times they had to approach health and social care services (e.g., GP visits, hospital admissions, care home or nursing home stays), and they would

be costed as per the national average tariff for each visit/use. This would be the end of the study, but patients will continue to have their clinical care and follow-up as per the local protocol of the study centre.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Health-related quality of life measured using EQ-5D-5L Questionnaire at 30(+15) days
2. Total cost incurred in patient treatment from the time of procedure until 30 days post-procedure, measured using cost collected from hospital finance department for procedure, investigation and hospitalisation costs, and national average cost for primary and social care resource use

Key secondary outcome(s)
Health economics:
1. Relative cost-effectiveness of the different TAVI valves over the estimated lifetime of treated patients, measured using cost of hospitalisation and primary and social care national average cost and then estimated over patient lifetime based on Office for National Statistics (ONS) data of the life expectancy of such participants
2. Quality-adjusted life years (QALYs) measured using EQ-5D-5L questionnaire country-specific index at 30 days and modelled over patients' lifetime
3. Incremental net monetary benefit (INMB) and incremental cost-effectiveness ratio (ICER) at 30 days, measured using mathematical/health economic calculations directly linked to quality of life and costs
4. Incremental cost per QALY at 30 days for each valve measured using mathematical calculation: cost of every device/QALY improvement with that device
5. Procedural efficiency (procedural time, contrast dose, radiation dose) measured using hospital paper or electronic records and direct input in electronic data capture (EDC) and electronic case report form (eCRF) by research staff at index procedure
6. Length of index hospital stay post-TAVI procedure, measured using hospital paper or electronic records
7. Rehospitalisation and number of days spent in hospital by 30 days, measured using hospital paper or electronic records
8. Resource use and costs to the NHS and social services at 30 days and modelled over the lifetime of patients, measured using direct costs calculation from hospital finance department and national average costs for primary care and social care resources over 30-day follow-up and then modelled based on the life expectancy of such patients

Clinical and echocardiographic:
1. Mortality (procedural, in-hospital, 30 days) measured using direct entry by research team in EDC using hospital paper or electronic record or ONS
2. Stroke (procedural, in-hospital, 30 days) measured using direct entry by research team in EDC using hospital paper or electronic record
3. Pacemaker implantation (in-hospital, 30 days) measured using direct entry by research team in EDC using hospital paper or electronic record
4. New York Heart Association (NYHA) class at 30 (+15) days
5. Disease-specific quality of life measured using Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12) at 30(+15) days
6. Technical success at exit of procedure based on Valve Academic Research Consortium 3 (VARC-3) criteria

7. Freedom from surgery or intervention related to the device or to a major vascular or access-related or cardiac structural complication (in-hospital, 30 days), measured using direct entry by research team in EDC using hospital paper or electronic record
8. Echocardiographic endpoints: mean aortic valve gradient, peak aortic valve gradient, peak aortic valve velocity, Doppler Velocity Index, effective orifice area, left ventricular ejection fraction (LVEF) and aortic regurgitation (in-hospital and/or within 30(+15) days post-TAVI)

Completion date
10/11/2027

Eligibility

Key inclusion criteria
1. Age >= 18 years
2. Informed consent to participate in the trial
3. Patients with severe aortic stenosis are eligible for TAVI with all the study devices as per the local heart team
4. TAVI planned via percutaneous transfemoral access

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
110 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Any participant who, in expert opinion of the local heart team, is not suitable for at least one of the study devices due to either technical limitations, high/unacceptable risk of complications if the device is implanted in that participant or reported hypersensitivity or allergy to any of the elements of the study device.
2. Participation in another clinical trial using TAVI devices not approved for routine clinical use
3. Participation in another trial which may affect cost outcomes
4. Patients undergoing any planned concomitant procedures, for example, percutaneous coronary intervention (PCI) or peripheral arterial stenting at the time of TAVI
5. Patient needing another planned surgery or procedure (for example, to treat a cancer) within 6 weeks of TAVI
6. The following patient groups will be excluded as they represent a small proportion of patients undergoing transfemoral TAVI in the UK and are associated with substantially different

procedural pathways and clinical risk profiles, which may introduce significant heterogeneity in short-term clinical outcomes and resource utilisation. Exclusion of these groups is intended to ensure comparability between treatment arms and preserve the internal validity of the cost-effectiveness analysis.
6.1. TAVI procedure planned under general anaesthesia (GA)
6.2. Patients with advanced kidney disease (CKD stage 4 or 5 or patients on haemodialysis)
6.3. Severely impaired left ventricular systolic function with ejection fraction (EF) less than 30%
6.4. Patient admitted to hospital for inpatient TAVI
6.5. TAVI in failed surgical aortic valve prosthesis with high risk of coronary obstruction requiring leaflet modification or coronary protection (VIVID class IIB, IIIB and IIIC)
6.6. Redo TAVI in failed TAVI prosthesis

Date of first enrolment
11/05/2026

Date of final enrolment
30/03/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
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Sponsor information

Organisation

Sheffield Teaching Hospitals NHS Foundation Trust

ROR
https://ror.org/018hjpz25

Funder(s)

Funder type
Government

Funder Name
Meril Life Sciences

Alternative Name(s)
Meril, Meril Life, Meril Life Sciences Pvt Ltd, Meril Life Sciences Pvt. Ltd., MLS

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
India

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date