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Does the alignment of a replacement artificial heart valve in the same direction as the patient’s own heart valve affect outcomes in aortic valve implantation? A feasibility study

Submission date
07/03/2023

Recruitment status
No longer recruiting

Registration date
20/04/2023

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Aortic valve stenosis is a type of heart valve disease in which the valve between the lower left heart chamber and the body's main artery (aorta) is narrowed and doesn't open fully. This reduces or blocks blood flow from the heart to the aorta and to the rest of the body. If symptoms become severe it will probably need surgery to replace the valve. A minimally invasive way of replacing a heart valve is through what is known as a transcatheter aortic valve implantation (TAVI) procedure. Currently, during a TAVI procedure, the new valve is not placed in the exact orientation of the old valve because it is not sure if this is possible. Part of this study is to try and see if the new valve can be put in the exact position of the old valve and if this will have an effect on how the valve functions. It is also postulated that orientating the valve in this way will make it easier to access the heart arteries if it is needed in future for any reason.

Who can participate?
Patients with severe aortic stenosis undergoing TAVI as decided by a structural heart multi-disciplinary team, who are aged between 70 and 100 years old and are considered clinically able to undergo all the procedures necessary for the intervention.

What does the study involve?
Patients referred for either outpatient or inpatient TAVI will be approached in the first instance by their clinical team. If the patient agrees to be approached by the research team, then this will take place. If informed consent is provided by the patient they will attend the TAVI procedure in the normal way. During the procedure, the replacement heart valve will be orientated in the same way as the patient’s own aortic valve. At the end of the TAVI, access to the heart arteries will be checked by catheters which are routinely used for heart artery angiograms and no dye will be injected. Overall the procedure should take no more than 10 minutes more than a standard TAVI procedure. A month later a return visit and CT scan checking the heart and arteries, will take place and this visit will take approximately 30 minutes.

What are the possible benefits and risks of participating?
It is unknown whether there will be an immediate benefit of taking part in the study beyond that expected from having your aortic valve replaced. However, the results of this study may benefit future patients having TAVI as it could improve our technique and knowledge of this procedure. There is a benefit of having the heart arteries assessed which may influence the patient's treatment. It is not believed that there are additional risks of taking part in the study over and above those involved with a standard TAVI procedure. However, there will be a CT scan after the TAVI which is one more scan than if not taking part.

Where is the study run from?
The Royal Sussex County Hospital Brighton (UK)

When is the study starting and how long is it expected to run for?
March 2022 to September 2023

Who is funding the study?
Terumo UK Ltd (UK)

Who is the main contact?
Dr Christopher Pavitt, christopher.pavitt@nhs.net (UK)

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
309300

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 309300

Study information

Scientific Title
Technical feasibility of neo-commissural alignment in Transcatheter Aortic Valve Implantation (TAVI): an exploratory study in patients undergoing TAVI describing procedural outcomes and effect on coronary artery access

Acronym
NeoTAVI

Study objectives
The study investigates whether aligning a replacement heart valve (TAVI) in the same orientation as the patient's own heart valve is feasible and facilitates access to coronary arteries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/05/2022, London - Surrey Borders Research Ethics Committee (Held remotely via Teleconference/ZOOM; +44 (0)207 104 8057, (0)207 104 8104, (0)207 104 8199; surreyborders.rec@hra.nhs.uk), ref: 22/PR/0394

Study design
Interventional feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Aortic stenosis

Interventions
Traditionally aortic valve replacement for patients with severe symptomatic aortic stenosis was achieved with surgical removal and implantation of a new mechanical or tissue valve necessitating cardiopulmonary bypass. Transcatheter aortic valve implantation (TAVI) or 'key-hole' surgery of the heart in a surgical setting has become the standard of care in replacing a diseased aortic valve in patients deemed a high or medium risk for conventional open surgical replacement, and recent data and guideline recommendations have extended its use to all surgical risk groups. Pre-procedural planning is of paramount importance and computer tomography (CT) has become the imaging modality of choice due to its high temporal and spatial resolution, and its ability to accurately delineate vascular structures. In this regard, the optimum vascular access route can be identified, and CT allows the operator to reliably measure the aortic root and size the TAVI valve accordingly. Evidence has shown that the use of CT has reduced procedural complication rates, such as aortic rupture, valve embolization and post-implant para-valvular leak.

Current practice is to implant the TAVI valve at a pre-determined depth, but unlike in surgical aortic valve replacement (AVR) in which the valve commissures are aligned to the native valve, the orientation and alignment of the TAVI valve is not routinely taken into consideration or deemed clinically necessary. There is growing evidence that achieving neo-commissural alignment with TAVI may improve valve haemodynamics and reduce valve hypo-attenuated

leaflet thrombosis (HALT), both of which may impact valve function. Furthermore, it may improve coronary access in patients requiring coronary artery intubation and facilitate repeat TAVI. Coronary access post-TAVI is attracting attention and is of particular importance as the number of TAVI implants grows and extends to younger patients who are more likely to require coronary intervention after valve replacement.

This single-arm, non-randomised study involves TAVI. Patients will be recruited for the study through the normal waiting list for aortic valve implantation at the University Hospitals Sussex NHS Foundation Trust. The team conducting the TAVI procedure are professors, consultants or specialised registrars in cardiology and electrophysiology. They are all registered with the GMC and have current Good Clinical Practice certification as well as training conforming to all the relevant standard operating procedures of the University Hospitals Sussex NHS Foundation Trust.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. TAVI valve alignment compared to patient's own aortic valve measured using cardiac-CT focusing on calculating the optimum commissural alignment during surgery
2. Coronary access using standard diagnostic catheters measured using CT-fractional flow reserve before and after the TAVI procedure

Secondary outcome measures
Computational fluid dynamics assessment of aortic blood flow measured using CT-fractional flow reserve before and after the TAVI procedure

Overall study start date
07/03/2022

Completion date
22/09/2023

Eligibility

Key inclusion criteria
Patients with severe aortic stenosis undergoing transcatheter aortic valve implantation (TAVI) as decided by the structural heart multi-disciplinary team (MDT)

Participant type(s)
Patient

Age group
Adult

Lower age limit
70 Years

Upper age limit
100 Years

Sex
Both

Target number of participants
30

Total final enrolment
30

Key exclusion criteria
1. Lack of vascular access to permit TAVI
2. Transaxillary or transcaval vascular access
3. Patient unable to undergo required post-TAVI CT-scan
4. Patient unable to give informed consent
5. Aged <70 or >100 years old
6. Decreased renal function eGFR <30ml/min
7. Pregnancy

Date of first enrolment
07/07/2022

Date of final enrolment
07/09/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Sussex County Hospital
Eastern Road
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Sponsor information

Organisation
University Hospitals Sussex NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
https://www.uhsussex.nhs.uk/

ROR
https://ror.org/03wvsyq85

Funder(s)

Funder type
Industry

Funder Name
Terumo UK Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
07/10/2024

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other unpublished results			17/01/2025	No	No