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A study of an abnormal heart rhythm occurring after transcatheter aortic valve implantation and its effect on survival - a United Kingdom experience.

Submission date
23/03/2015

Registration date
30/04/2015

Last Edited
13/07/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
With every heartbeat the aortic valve opens to allow blood to leave the main pumping chamber of the heart to supply the tissues and organs of the human body. Over time and as a natural consequence of ageing, the aortic valve leaflets (there are usually three) can become stiff, open less well and the valve opening (orifice) is narrowed as a result. This is called aortic valve stenosis, which is the most common form of heart valve disease in the developed world. The aortic valve orifice can become so narrowed that an individual can become symptomatic and suffer chest pain, shortness of breath, a reduction in exercise capacity and loss of consciousness. Before these symptoms can take hold it is standard medical practice for the patient to be considered for aortic valve replacement via open heart surgery. Indeed severe symptomatic aortic stenosis is often fatal if left untreated, whilst timely relief of the mechanical obstruction can restore normal life expectancy. Surgical aortic valve replacement is an operation associated with a small but significant risk of death and other complications. In those patients who may be frail and/or suffer other medical problems, that risk may be heightened to such an extent that the benefits of the operation may be outweighed by the risks attached. In the past, patients declined for an aortic valve operation would have no other alternative but to continue their tablet therapy. In 2002, the first transcatheter aortic valve implantation (TAVI) procedure was performed. This was a new method of replacing the aortic valve without having to perform open heart surgery. With TAVI a replacement aortic valve, fashioned from cow or pig heart tissue mounted on an expandable metallic frame, is placed across the native aortic valve via a main artery in the groin, chest, or neck or directly through the bottom tip of the heart via a small incision in the lower left ribcage. The TAVI procedure has now become established as a therapeutic strategy for the management of severe aortic stenosis in those patients who do not qualify for a surgical aortic valve replacement. The close proximity of the aortic valve apparatus to the native electrical conduction system of the heart lends to an increased propensity for the development of excessively slow heart rhythms. Following traditional surgical aortic valve replacement, for instance, a permanent pacemaker is required in 2-8% of patients postoperatively to prevent the heart rate from falling too low. Following a TAVI procedure the

occurrence of electrical conduction abnormalities can be even higher. For the purposes of the 3B Study, we are focusing on a specific heart rhythm abnormality called Left Bundle Branch Block (LBBB), which has been noted to occur following a small percentage of TAVI procedures. The exact percentage of patients likely to suffer LBBB following a TAVI procedure is unknown as is its relation to harmful complications such as an impairment in the overall pumping function of the heart, and more seriously, whether the emergence of LBBB can increase the likelihood of death following a TAVI procedure. We will study, in a retrospective fashion, all the TAVI procedures that have taken place since the inception of the service at each participating institution up until the 31st of December 2013. This study will represent the largest database of TAVI procedures in which the occurrence of LBBB post procedure has been analysed in the medical literature to date. The information gleaned from the study will help us to determine the prognostic significance of LBBB post TAVI procedure. If LBBB is found to be detrimental to the survival of patients post TAVI, further studies can then be designed to determine what therapeutic interventions can be put in place to improve outcome in this specific patient subgroup.

Who can participate?
Patients undergoing the TAVI procedure at one of the participating centres within the period from the start of the TAVI programme at their trial participating centre until the 31st December 2013.

What does the study involve?
For all the participants in the study we will determine: (1) how many developed LBBB following TAVI; (2) whether the development of LBBB led to an increased risk of death within a year following the TAVI operation; (3) whether the development of LBBB led to an increased risk of death from a cardiovascular cause 1 year after the TAVI operation; and (4) whether the development of LBBB led to a reduction in the pumping function of the heart at 30 days and at 1 year after the TAVI operation.

What are the possible benefits and risks of participating?
There are no benefits of risks associated with taking part in this study

Where is the study run from?
A total of 18 NHS hospitals across the UK

When is the study starting and how long is it expected to run for?
February 2015 to December 2015

Who is funding the study?
King's College London (UK)

Who is the main contact?
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Type(s)
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1.0

Study information

Scientific Title
New left bundle branch block following transcatheter aortic valve implantation and its effect on survival - a United Kingdom experience.

Acronym
The 3B Investigators Study

Study objectives
New onset left bundle branch block after successful transcatheter aortic valve implantation increases 1-year all cause mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Service (NRES) Committee North West - Lancaster of the National Health Service of the United Kingdom, 18/11/2014, ref: 14/NW/1456

Study design
A retrospective United Kingdom multi-centre observational registry

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Transcatheter aortic valve implantation for the percutaneous treatment of calcific degenerative aortic valve stenosis.

Interventions
Left bundle branch block (LBBB) is the most common conduction abnormality following transcatheter aortic valve implantation (TAVI). Whilst LBBB in the post surgical and heart failure population is known to carry a poor prognosis, the prognostic significance of new LBBB following TAVI is less well delineated. TAVI-induced LBBB has been shown to negatively affect cardiac function and increase re-hospitalisation, although its direct impact on mortality remains a subject of increasing relevance and continuing debate. This UK-wide retrospective observational registry aims to gain further insight into the prognostic significance of newly diagnosed LBBB in all patients undergoing successful TAVI device implantation (irrespective of device manufacturer) from inception of the TAVI programme at a participating institution to the 31st of December 2013.

Intervention Type
Procedure/Surgery

Primary outcome measure
All-cause mortality at 1 year following transcatheter aortic valve implantation.

Secondary outcome measures
1. Cardiovascular mortality at 1 year following transcatheter aortic valve implantation
2. Need for permanent pacemaker implantation following transcatheter aortic valve implantation
3. Left ventricular ejection fraction at 30 days and at 1 year following transcatheter aortic valve implantation

Overall study start date
18/02/2015

Completion date
01/12/2015

Eligibility

Key inclusion criteria
All patients undergoing successful transcatheter aortic valve implantation (TAVI), irrespective of device manufacturer, from the inception of the TAVI programme at the participating institution until the 31st December 2013

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Previous/pre-existing permanent pacemaker in situ
2. Unsuccessful transcatheter aortic valve implantation procedure

Date of first enrolment
18/02/2015

Date of final enrolment
01/12/2015

Locations

Countries of recruitment
England

United Kingdom

Virgin Islands, U.S.

Study participating centre
Guy's and St Thomas' NHS Foundation Trust
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
University Hospital Southampton NHS Foundation Trust
Tremona Road
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SO16 6YD

Study participating centre
Brighton and Sussex University Hospitals NHS Trust
177 Preston Road
Brighton
United Kingdom
BN1 6AG

Study participating centre
Oxford University Hospitals NHS Trust
Level 3, John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
The London Chest Hospital, Barts Health NHS Trust
Bonner Road
London
United Kingdom
E2 9JX

Study participating centre
University Hospitals Bristol NHS Foundation Trust
Upper Maudlin Street
Bristol
United Kingdom
BS2 8HW

Study participating centre
Liverpool Heart and Chest Hospital NHS Foundation Trust
Thomas Drive
Liverpool
Merseyside
United Kingdom
L14 3PE

Study participating centre

University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Medical Centre
Birmingham
Virgin Islands, U.S.
B15 2TH

Study participating centre
Papworth Hospital NHS Foundation Trust
Papworth Everard
Cambridge
United Kingdom
CB23 3RE

Study participating centre
Hammersmith Hospital, Imperial College Healthcare NHS Trust
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre
University Hospital of North Staffordshire NHS Trust
Newcastle Road
Stoke-on-Trent
Staffordshire
United Kingdom
ST4 6QG

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
United Kingdom
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Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle-upon-Tyne
United Kingdom
-

Study participating centre
Royal Victoria Hospital, Belfast Health and Social Care Trust
Belfast
United Kingdom
-

Study participating centre
Plymouth Hospitals NHS Trust
Plymouth
United Kingdom
-

Study participating centre
Leeds Teaching Hospitals NHS Trust
Leeds
United Kingdom
-

Study participating centre
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

Funder(s)

Funder type
University/education

Funder Name
King’s College London

Alternative Name(s)
Collegium Regale Londiniense, King's, KCL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We intend to publish a methods/protocol paper very shortly which will detail the study design as already described on the ISRCTN registry application. Thereafter the main results paper will be submitted to a major international general medical journal.

Intention to publish date
01/09/2018

Individual participant data (IPD) sharing plan
Participant level data has been analysed statistically and the results of said analysis will be described in the manuscript currently being written. If the journal requires us to include parts of the dataset in an unidentifiable form in the Supplementary Appendix, we shall do so. The entire dataset includes over 1200 individual patient records and will be held on password-protected institutional databases.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Basic results	03/04/2019	03/04/2019	No	No
HRA research summary		28/06/2023	No	No