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Evaluation of a new type of heart valve - a single-center experience

Submission date	Recruitment status	[_] Prospectively registered
06/11/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/11/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Aortic stenosis is a condition where the aortic valve of the heart becomes narrowed and stiff due to a build-up of calcium. In patients with aortic stenosis and a high or extreme risk for open surgery, transcatheter aortic valve implantation (TAVI) is the first line treatment. TAVI is a way of replacing the valve with a new valve (prosthesis) which is inserted through a small incision in the groin or through the chest wall, thereby improving how the heart works without the need for open heart surgery. There are several different types of TAVI prosthesis with different characteristics. The Lotus valve is a new and promising valve which enables the doctors to reposition or even remove the valve if they are unhappy with the position or the size of the valve. This offers a unique safety aspect of the device. A seal outside the valve also minimizes leak after implantation. The main drawback of the valve is that in previous studies, it has been associated with a 30 % risk of needing a pacemaker after implantation. The aim of this study is to assess the valve with regards to a new implantation technique aimed at reducing the risk of pacemaker after implantation.

Who can participate?
Patients aged over 18 who are eligible for TAVI and implantation with a Lotus Valve

What does the study involve?
Routinely collected data is used to assess the safety and effectiveness of the 100 first successful Lotus Valve implantations after 30 days and 12 months. Device success, mortality (death rate), pacemaker implantation rate, major complications, stroke and leak are all assessed.

What are the possible benefits and risks of participating?
All parts of this study are routine care for the patient and the data is routinely collected. This study doesn't require any extra examinations or undertakings for the patients. There are no particular risks or benefits associated with this study as it is part of follow-up of routine care.

Where is the study run from?
Skane University Hospital (Sweden)

When is the study starting and how long is it expected to run for?
September 2013 to December 2016

Who is funding the study?
Skane University Hospital Cardiology Fund (Sweden)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Lotus 1.1

Study information

Scientific Title
Single-center evaluation of a next generation fully repositionable and retrievable transcatheter aortic valve replacement

Study objectives
The rationale of this study was to evaluate the short- and long-term safety and efficacy of the new device with focus on a new implantation technique to reduce the need for a permanent pacemaker (PPM) post procedure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lund University ethics committee, 01/05/2009, ref: LU2009/87

Study design
Single-centre observational study

Primary study design
Observational

Secondary study design
Cohort study

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
Patients with severe symptomatic aortic stenosis with high or extreme surgical risk eligible for TAVI

Interventions
The 30-day and 12-month safety and efficacy of the 100 first successful Lotus Valve implantations will be evaluated in a prospective non-randomized registry.

Intervention Type
Device

Primary outcome measure
Device success according to VARC 2 criteria (periprocedural)

Secondary outcome measures
1. Mortality at 30 days and 12 months
2. Pacemaker implantation rate at discharge, 30 days and 12 months
3. Major vascular complications at discharge
4. Stroke at 30 days
5. Paravalvular leak at discharge and 12 months

Overall study start date
19/09/2013

Completion date

01/12/2016

Eligibility

Key inclusion criteria
1. >18 years old
2. Eligible for TAVI and eligible for implantation with a Lotus Valve as assessed by the interdisciplinary Heart Team

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
100

Key exclusion criteria
1. <18 years old
2. Other co-morbidity with expected life span <12 months

Date of first enrolment
19/09/2013

Date of final enrolment
19/09/2015

Locations

Countries of recruitment
Sweden

Study participating centre
Skane University Hospital
Lund
Sweden
22185

Sponsor information

Organisation
Skane University Hospital

Sponsor details
Department of Cardiology
Getingevagen 4
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Sponsor type
University/education

ROR
https://ror.org/02z31g829

Funder(s)

Funder type
University/education

Funder Name
Skane University Hospital Cardiology Fund

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal. Since this is a registry study, no additional documents will be available.

Intention to publish date
01/12/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository, but due to local regulation, it will not be publically available unless upon specific request of limited datasets.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/02/2019	18/12/2019	Yes	No