A Feasibility Study to Assess Safety and Efficacy of the Transapical and Transfemoral JenaValve Pericardial TAVR System in the Treatment of Patients with Symptomatic Severe Aortic Stenosis (AS) (CA-0001)/ Symptomatic Severe Aortic Regurgitation (AR) (CA-0002)

Published: 20-01-2016
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Ethical review	Approved WMO
Status	Completed
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON46960

Source
ToetsingOnline

Brief title
JenaValve AS/AR Feasibility Study

Condition

- Cardiac valve disorders

Synonym
leaking heart valve, narrow heart valve

Research involving
Human

Sponsors and support

Primary sponsor: JenaValve Technology, Inc.
Source(s) of monetary or material Support: Industry;JenaValve Technology;Inc.

Intervention

Keyword: aortic regurgitation, aortic stenosis, transcatheter aortic valve replacement (TAVR), transcatheter heart valve

Outcome measures

Primary outcome

Thirty (30)-day post-index procedure all-cause mortality (adjudicated).

Secondary outcome

Study endpoints are defined according to the standardized endpoint definitions

for transcatheter aortic valve implantation as outlined in The Valve Academic

Research Consortium-2 consensus document (i.e. VARC-2).

Study description

Background summary

This is a feasibility clinical study sponsored by JenaValve Technology, Inc. (the *Sponsor*) to help evaluate a new device (JenaValve Pericardial TAVR System) to treat subjects who require replacement of their aortic heart valve due to symptomatic severe aortic stenosis (narrow valve) or aortic regurgitation (leaking valve).

Study objective

The objective of this study is to evaluate the safety and efficacy of the transapical and transfemoral JenaValve Pericardial TAVR System in treating subjects with symptomatic severe aortic stenosis or symptomatic severe aortic regurgitation requiring replacement of their native aortic valve who are at high risk for open surgical aortic valve replacement (SAVR) and deemed to be

non-surgical candidates using a minimally invasive transcatheter aortic valve replacement (TAVR) procedure. The study protocol will ensure consistency in the performing the procedure, patient management, and results of the procedure. The results of this study shall be used to support a design dossier for CE Mark approval of the JenaValve Pericardial TAVR System for treatment of aortic stenosis/ aortic regurgitation.

Study design

This is a prospective, multicenter, single-arm, feasibility study evaluating the safety and efficacy of transcatheter aortic valve replacement utilizing the JenaValve Pericardial TAVR System for the treatment of aortic stenosis or aortic regurgitation.

Intervention

Minimally invasive procedure: transcatheter aortic valve implantation (TAVI). Also known as transcatheter aortic valve replacement (TAVR).

Study burden and risks

Burden:
Other than standard treatment laboratory measurements and echocardiography will be performed at 6-month and 2-year follow-up. The 6 min Walking test and the Kansas City Cardiomyopathy Questionnaire will be asked to be completed at Baseline and at 1-, 2-year follow-up. The Modifed Rankin Scale (mRS) will be performed at Baseline for any study patient reported with a history of stroke. For any patient reported with new-onset stroke, the mRS will be performed initially upon the diagnosis of stroke and then at each follow-up interval until study completion.

Possible risks:
There are currently no known additional risks with the specific use of the JenaValve Pericardial TAVR System. As with any medical treatment, there may be risks that we do not know about at this time. Women who are pregnant may not participate in this study. If you are of child bearing potential you will be required to take a pregnancy test before you participate in this study.

Possible benefits:
• Help return the heart to its regular function.
• Decreased risk of surgery complications (such as bleeding after surgery).
• Possibility to treat aortic regurgitation.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Adult patients with symptomatic severe aortic stenosis or symptomatic severe aortic regurgitation who are at high risk for surgical aortic valve replacement

Exclusion criteria

Congenital uni- or bicuspid aortic valve morphology, previous prosthetic aortic valve implant, mitral regurgitation greater than moderate

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	29-02-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	JenaValve Pericardial TAVR System
Registration:	No

Ethics review

Approved WMO

Date:	20-01-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-07-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	16-11-2016
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	10-04-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	08-11-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL54175.058.15

Study results

Date completed:	19-02-2024
Results posted:	08-05-2024
Actual enrolment:	0

First publication
01-01-1900