Safety and Performance Study of the Edwards CENTERA Self-Expanding Transcatheter Heart Valve.

Published: 18-05-2015
Last updated: 14-04-2024

The purpose of this study is to assess the safety and device success of the Edwards CENTERA Transcatheter Heart Valve (THV) System in patients with symptomatic, severe aortic stenosis who are indicated for aortic valve replacement.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON44006

Source
ToetsingOnline

Brief title
CENTERA 2014-03

Condition

- Cardiac valve disorders

Synonym
severe heart valve contraction, symptomatic aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Edwards Lifesciences LLC
Source(s) of monetary or material Support: Edwards Lifesciences

Intervention

Keyword: European safety and performance study, Selfexpanding Transcatheter Heart Valve (THV), Symptomatic patient with severe aortic stenosis

Outcome measures

Primary outcome

All-cause mortality at 30 days post-index procedure

Secondary outcome

Device Success:

Composite of absence of procedural mortality AND correct positioning of a

single prosthetic heart valve into the proper anatomical location AND intended

performance of the prosthetic heart valve (no prosthesis-patient mismatch and

mean aortic valve gradient <20 mmHg or peak velocity <3 m/s, with no moderate

or severe prosthetic valve regurgitation) per echo assessment at 30 days.

Safety endpoints:

1. Composite of mortality, stroke, major vascular complication,

life-threatening bleeding, acute kidney injury (Stage 2 or 3), coronary artery

obstruction requiring intervention, and THV-related dysfunction requiring

repeat procedure at 30 days;

2. Peri-procedural mortality (<=72 hours);

3. Cardiac mortality (including any valve-related dysfunction of any

valve-related adverse event) at 30 days,6 months, and 1 year;

4. Stroke at 1 year post-index procedure;

5. Major bleeding complications during procedure, at hospital discharge (or 72

hours, whichever is longer), and 30 days post-index procedure;

6. Myocardial infarction (MI) within 72 hours, 30 days, 6 months, and 1 year post-index procedure;

7. New conduction abnormality (AV block I, II, III, LBBB, RBBB, etc.) at hospital discharge (or 72 hours, whichever is longer), 30 days, 6 months, and 1 year post-index procedure;

8. New onset atrial fibrillation at hospital discharge (or 72 hours, whichever is longer), 30 days, 6 months, and 1 year post-index procedure;

9. Time-related valve safety composite of valve structural deterioration a) requiring repeat procedure (transcatheter or surgical heart valve replacement) or b) evidenced by mean aortic valve gradient >=20 mmHg, EOA <=0.9-1.1 cm2* and/or DVI<0.35, AND/OR moderate or severe prosthetic valve regurgitation, prosthetic valve endocarditis, prosthetic valve thrombosis, thromboembolic events (e.g. stroke), and bleeding that is not clearly unrelated to valve therapy (e.g. trauma).

Clinical efficacy endpoints:

1. Composite of all-cause mortality, all stroke, re-hospitalization for valve-related symptoms or worsening congestive heart failure, NYHA Class III or IV, prosthetic valve dysfunction (mean aortic valve gradient >=20 mmHg, EOA <=0.9-1.1 cm2 and/or DVI<0.35, AND/OR moderate or severe prosthetic valve regurgitation) at 30 days, 6 months, and one year;

2. Re-hospitalization for valve-related symptoms or worsening congestive heart failure at 30 days, 6 months,and one year;

3. NYHA class at 30 days, 6 months, and one year;

4. Six minute walk test (6MWT) at 30 days;

5. Quality of Life instrument EQ5D at 30 days, and one year;

6. Length of stay for Intensive/Cardiac Care Unit, Intermediate Care Unit, and standard ward and total index procedure.

Echocardiographic endpoints:

1. Paravalvular and total aortic regurgitation at discharge, 30 days, 6 months, and 1 year;

2. Indexed effective orifice area at discharge, 30 days, 6 months, and 1 year;

3. Mean aortic valve gradient at discharge, 30 days, 6 months, and 1 year;

4. Structural valve deterioration requiring repeat transcatheter or surgical aortic valve replacement (TAVI or SAVR) at 1 year;

5. Prosthetic valve dysfunction evidenced by mean aortic valve gradient >=20 mmHg, EOA <=0.9-1.1 cm2 and/or DVI<0.35, AND/OR moderate or severe prosthetic valve regurgitation at discharge, 30 days, 6 months, and 1 year;

6. LV Ejection fraction at 30 days, 6 months, and 1 year.

Study description

Background summary

The CENTERA design builds upon the extensive clinical experience of the previous SAPIEN and SAPIENT XT valves, but implemented in a nitinol frame. The CENTERA THV System represents the first self-expanding stent-valve model developed by Edwards Lifesciences, and it is indicated for use in symptomatic patients with severe aortic stenosis requiring aortic valve replacement (AVR)

with a high surgical risk (8 <= STS Score <= 15 or 15 <= EuroSCORE I <= 40).

Study objective

The purpose of this study is to assess the safety and device success of the Edwards CENTERA Transcatheter Heart Valve (THV) System in patients with symptomatic, severe aortic stenosis who are indicated for aortic valve replacement.

Study design

This is a non-randomized, prospective, multi-center safety and device success study. Up to two hundred (200) patients are planned to be implanted at up to 25 participating investigational centers in Europe. Patient participation will last for a minimum of 5 years. Patients will be assessed at the following intervals: baseline, hospital discharge, 30 days, 6 months, 1 year and annually thereafter through 5 years.

Intervention

All study subjects will receive a non-CE marked heartvalve.

Study burden and risks

The additional burden for the participating patients will concern the six-minute walking tests and the questionnaires about their quality of life. The usual risks of a percutaneous aortic valve replacement also apply here, and when the motor system does not work properly, the doctor would have to withdraw the catheter/ sheath manually.

Contacts

Public
Edwards Lifesciences LLC

One Edwards Way .
Irvine CA 92614
US
Scientific
Edwards Lifesciences LLC

One Edwards Way .
Irvine CA 92614
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Heart team (including at least a cardiac surgeon and an interventional cardiologist) agrees on eligibility including assessment that TAVI is appropriate.
2. High surgical risk: 8 <= STS Score <= 15 or 15 <= Logistic EuroSCORE I <= 40.
• if STS score is below 8 and/or EuroSCORE is below 15,the Heart Team must document other clinical or anatomical risk factors for which the patient would be considered high risk for surgery.
3. NYHA >= II.
4. Severe symptomatic aortic stenosis requiring aortic valve replacement characterized by AVA <= 1cm2 (or indexed AVA <0.6 cm2/m2) or mean gradient > 40mmHg (or peak aortic jet velocity > 4.0m/sec).
5. Study patient is an adult of legal consent age.
6. Study patient has provided written informed consent to comply with all of the study procedures and follow-up visits.
7. If women of childbearing age, confirmation of negative pregnancy test

Exclusion criteria

1. Evidence of an acute myocardial infarction <= 1 month (30 days) before the intended treatment [(defined as: Q wave MI, or non-Q wave MI with elevation of CK-MB >= 3 times normal in the absence of pathological Q waves), if no assay for CK-MB was performed, elevation of CK level to > 2 times normal without new Q waves is also considered a non-Q wave MI)].
2. Untreated clinically significant coronary artery disease requiring revascularization.
3. Aortic valve is a congenital unicuspid or congenital bicuspid valve.
4. Mixed aortic valve disease (aortic stenosis and aortic regurgitation with predominant aortic regurgitation >3+).
5. Preexisting bioprosthetic valve or ring in any position.

6. Leukopenia (WBC < 3000 cell/µL), anemia (Hgb < 9 g/dL), Thrombocytopenia (Plt < 50,000 cell/µL), or any known blood clotting disorder.
7. Non-valvular hypertrophic cardiomyopathy with or without obstruction (HOCM).
8. Severe ventricular dysfunction with LVEF < 20%.
9. Echocardiographic evidence of intracardiac or intraaortic mass, thrombus or vegetation.
10. Active upper GI bleeding within 3 month (90 days) prior to procedure.
11. A known contraindication or hypersensitivity to all anticoagulation regimens, or inability to be anticoagulated for the study procedure.
12. Native aortic annulus size < 18 mm or > 26 mm as measured by CT.
13. Clinically (by neurologist) or neuroimaging confirmed stroke or transient ischemic attack (TIA) within 3 months (90 days) of the procedure.
14. Renal insufficiency (creatinine > 3.0 mg/dL) and/or renal replacement therapy at the time of screening.
15. Estimated life expectancy < 24 months (730 days) due carcinomas, chronic liver disease, chronic renal disease or chronic end stage pulmonary disease.
16. Expectation that patient will not improve despite treatment of aortic stenosis.
17. Currently participating in an investigational drug or another device study. Note: Trials requiring extended follow-up for products that were investigational, but have since become commercially available, are not considered investigational trials.
18. Active infection at the time of procedure and/or bacterial endocarditis within 6 months (180 days) of procedure.
19. Access vessel characteristics that would preclude safe placement of a minimum 14F sheath, which may include any of the following: severe obstructive calcification, severe tortuosity, or minimum vessel diameter less than 0.5mm.
20. Known hypersensitivity to nitinol (nickel or titanium) or contrast media that cannot be adequately premedicated.
21. PCI within one month (30 days) prior to the TAVI procedure.
22. Emergency interventional/surgical procedures within one month (30 days) prior to the TAVI procedure.
23. Severe mitral insufficiency.
24. Pregnant or breastfeeding women

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2015
Enrollment:	45
Type:	Actual

Medical products/devices used

Generic name:	CENTERA Self-Expanding Transcatheter Heart Valve
Registration:	No

Ethics review

Approved WMO Date:	18-05-2015
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	29-07-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	14-09-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	23-10-2015
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	29-02-2016
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-03-2016

Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	13-11-2018
Application type:	Amendment
Review commission:	METC NedMec

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	NL51736.041.15

Study results

Date completed:	28-09-2021
Actual enrolment:	9

Summary results
Trial is onging in other countries