Edwards SAPIEN* Aortic Bioprothesis European Outcome Registry

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The main registry objective is to observe the safety and efficacy outcomes in patients where treatment of severe calcific degenerative aortic stenosis was intended with the commercially available Edwards SAPIEN* Valve.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac valve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON32862

Source
ToetsingOnline

Brief title
SOURCE REGISTRY

Condition

- Cardiac valve disorders

Synonym
Aortic Valve Stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Edwards SAPIEN Aortic Bioprothesis, Efficacy, Outcome, Safety

Outcome measures

Primary outcome

Collect the safety and efficacy outcomes data of the commercially available Edwards SAPIEN* Valve intended for the treatment of severe calcific degenerative aortic stenosis at discharge or <7 days, and 30 days.

Secondary outcome

Collect the safety and efficacy outcomes data of patients who received the commercially available Edwards SAPIEN* Valve for the treatment of severe calcific degenerative aortic stenosis at 1 year.

Study description

Background summary

This registry is part of our post-marketing surveillance required by the Notified Body. We have a limited CE mark for 1year, to prolonge our CE mark we have to conduct this registration. The Notified Body is especially looking at 30 day mortality.

Study objective

The main registry objective is to observe the safety and efficacy outcomes in patients where treatment of severe calcific degenerative aortic stenosis was intended with the commercially available Edwards SAPIEN* Valve.

Study design

This is a multi-center, observational European registry. A minimum of 300 patients are to be enrolled in commercial sites. Each site will register at least 10 patients. Patient hospitalization data should be collected from the index procedure to discharge or <7 days post procedure (whichever comes first)

and at 30 days and 12 months post procedure.

Study burden and risks

Not Applicable

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

the SAPIEN* valve is indicated for use in patients with symptomatic aortic stenosis (aortic valve area <0.8cm²) requiring AVR who have high risk for operative mortality, or are *non-operable*, as determined by either or both of the
following risk assessments:

• Logistic Euro SCORE >20% or
• STS Risk score >10

Exclusion criteria

1. Non-valvular aortic stenosis
2. Congenital aortic stenosis, unicuspid or bicuspid aortic valve
3. Non-calcific acquired aortic stenosis
4. Evidence of intracardiac mass, thrombus or vegetation
5. Untreated clinically significant coronary artery disease requiring revascularization
6. Severe deformation of the chest
7. Severe coagulation problems
8. Active bacterial endocarditis or other active infections
9. Myocardial infarction(MI) within one month
10. Unstable angina during index procedure
11. Recent pulmonary emboli
12. Recent(within 6 months) cerebrovascular accident (CVA)
13. Patients unable to tolerate anticoagulation therapy
14. Significant atheroma of femoral and iliac vessels
15. Severe tortuosities of the femoro-iliac vessels
16. Femoro-iliac vessels < 7mm
17. Patients with bilateral iliofemoral bypass
18. Hypertrophic cardiomyopathy with or without obstruction (HOCM)
19. Severe ventricular dysfunction with ejection fraction < 20%

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-04-2009
Enrollment:	10

Type:	Actual

Ethics review

Approved WMO Date:	24-11-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL24051.058.08