MISSION-Registry: Assessing clinical outcomes using the EDWARDS INTUITY Elite Valve Systyem in isolated AVR using Minimally InvaSive Surgery In a EurOpean multi-ceNter, active, post-market registry.

Published: 15-09-2016
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Primary Objective:To compare the Cross Clamp Time collected with EDWARDS INTUITY Elite to published data with a conventional valve within a MIS approachSecondary Objectives:To describe short term (30 days) and long term (6 months) clinical safetyTo...

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

Summary

ID

NL-OMON45758

Source
ToetsingOnline

Brief title
MISSION-Registry

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
aortic valve stenosis, heart valve restriction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: invasive, minimally, sutureless, valve

Outcome measures

Primary outcome

Aortic Cross Clamp time

Secondary outcome

Secondary endpoints:

Cardiopulmonary bypass time

Procedure time

Valve implant time

Device technical success (defined as the successful delivery and deployment of a study valve and delivery system and subject leaving the operating room with valve in place)

First Attempt Success Rate

ICU and Hospital Length of Stay

Hemodynamic performance (mean gradient, peak gradient, effective orifice area [EOA], EOA index, performance index, cardiac output [CO], cardiac index [CI], valvular regurgitation [including paravalvular leak]) confirmed by an Echocardiographic Core Laboratory at Discharge and 6 months (if available)

Patient related endpoints:

NYHA functional class compared to baseline

Change in Quality of Life questionnaire Form 36 (SF-36) and EQ-5D from

Screening to 6 months

Fitness for hospital Discharge

Safety endpoints:

Complication rates at 30 days (early rates) and at 6 months :

All cause mortality

o Study valve-related mortality

Thromboembolism

o Stroke

o TIA

o Non cerebral embolism

Valve Thrombosis

Major Bleeding event

Endocarditis (study valve)

Structural valve deterioration

Non Structural valve deterioration

o Paravalvular Leak minor

o Paravalvular Leak major

o Other non SVD

Reoperation

o Trial valve reoperation

Hemolysis

Study valve explants

Implant-related new or worsened cardiac conduction disturbance requiring

permanent pacemaker implant

Renal Failure

Respiratory dysfunction

Deep Sternal Wound infection

The Clinical Events Committee (CEC) will evaluate the

adverse events including adverse events resulting in death as outlined in their

charter and adjudicate these events for their relatedness to the

investigational device, and the investigational device procedure.

Study description

Background summary

The EDWARDS INTUITY Elite System has been designed to facilitate minimally invasive surgery (MIS) introduction of the bioprosthetic valve.
This active, open-label, non-randomized, post-market study will describe in a real world cohort, procedural, clinical and hemodynamic outcomes of Minimally

Invasive Surgery (MIS) for isolated Aortic valve Replacement (AVR) in the context of EDWARDS INTUITY Elite Valve System.
Patient assessments will be done according to standard of care.
The primary hypothesis of the study is that EDWARDS INTUITY Elite reduces cross clamp time (XCT) in MIS setting when compared to published data with a conventional valve in the same setting.

Study objective

Primary Objective:
To compare the Cross Clamp Time collected with EDWARDS INTUITY Elite to published data with a conventional valve within a MIS approach

Secondary Objectives:
To describe short term (30 days) and long term (6 months) clinical safety
To assess and compare hemodynamic data with EDWARDS INTUITY Elite to a conventional valve at discharge and at 6 months post AVR
To assess Quality of Life at baseline, and at 6 months post AVR
To assess NYHA functional class at baseline, discharge, 1 month and at 6 months post AVR
To assess Fitness for hospital discharge

Study design

This multi-center registry is open-label, prospective, single arm and non-randomized.
Baseline characteristics of subjects shall be collected. Risk scores (Euroscore I and II) will be collected by registry sites.
Intra-operative data including cross-clamp time (XCT), bypass times, procedure times and first implant success will be recorded. The intensive care unit (ICU), total hospital durations and fitness to hospital discharge will be recorded. All adverse events will be recorded.
Early postoperative (* 30 days) safety data will be collected to evaluate short term outcomes.
Quality of Life will be collected at baseline and 6 months (EQ-5D and SF-36).
Follow-up data will be collected and evaluated at 6 months.
Patient assessments will be done according to standard of care.

Study burden and risks

Patients need to fill in two questionnaires preoperatively. This will take approximately 15 minutes. These questionnaires will be repeated after 6 months. This will also take approximately 15 minutes. Also, a phonecall shall be made 30 days after surgery. This will take 5 minutes. Six months after surgery an ultrasound of the heart will be made and the questionnaires will be filled in again. Also, blood tests will be done at that time. This will take

approximately one hour. In total the burden for the patients shall amount to approximately 2 hours (not including time needed for traveling to the hospital).

The risks associated with participation in this trial regarding the minimally invasive procedure are comparable with the risks associated with the conventional treatment.

Contacts

Public
Edwards Lifesciences SA

Route de l'Etraz 70
Nyon 1260
CH
Scientific
Edwards Lifesciences SA

Route de l'Etraz 70
Nyon 1260
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Subject is 18 years or older
2. Subject is symptomatic for aortic stenosis (AS) or mixed aortic stenosis and aortic insufficiency (AS/AI) disease for which isolated surgical aortic valve replacement without

concomitant procedures is indicated according to International guidelines.
3. Surgery starts with and is intended to be completed via a minimal invasive surgical approach. MIS is defined as a non-full sternotomy approach such as partial hemi-sternotomy, right anterior thoracotomy.
4. Subject has signed and dated the investigation informed consent forms prior to any study-specific procedures are performed.
5. Subject is geographically stable and agrees to attend follow-up assessments as specified in the protocol and informed consent.

Exclusion criteria

1. Subject is diagnosed with pure aortic insufficiency.
2. Subject requires multiple valve replacement/repair
3. Subject has Type 0 congenital true bicuspid aortic valve (i.e. absence of raphe and commissures are positioned about 180 degrees apart) or unicuspid aortic valve.
4. Subject has severe ventricular dysfunction defined as LVEF < 25%.
5. Subject has a history of active endocarditis and/or myocarditis * 3 months before the intended treatment/scheduled surgery.
6. Subject has had an acute MI * 3 months before the intended treatment.
7. Subject had a stroke or transient ischemic attack within six months prior to scheduled aortic valve replacement surgery.
8. Subject is oxygen or ventilator dependent.
9. Subject has life expectancy < 12 months.
10. Female subject is pregnant or lactating.
11. Subject with documented leukopenia (WBC < 3.5x 103/*L), acute anemia (Hb < 10.0 gm/dL or < 6.2 mmol/L), thrombocytopenia (platelet count < 100x 103/mL), or history of bleeding diathesis or coagulopathy.
12. Subject has hemodynamic or respiratory instability requiring inotropic support, mechanical circulatory support, or mechanical ventilation within 1 month of procedure.
13. Subject has documented echocardiographic evidence of intracardiac mass, thrombus or vegetation.
14. Subject has renal insufficiency as determined by Serum creatinine * 200 *mol/L (2.27 mg/dL) at screening or end-stage renal disease requiring chronic dialysis.
15. Subject with documented hyperparathyroidism.
16. Subject is currently participating in an investigational drug or device trial for which follow-up has not yet been completed.
17. Minimally Invasive access to the heart is not possible due to anatomical constraints or any other pre-existing condition.
18. Aneurysm of the aortic root and/or ascending aorta;Intra-operative exclusion criteria:
1. Subject has Type 0 congenital true bicuspid aortic valve (i.e. absence of raphe and commissures are positioned about 180 degrees apart) or unicuspid aortic valve. (A non-congenital bicuspid valve without a distorted annulus would not be cause for exclusion.)
2. Subject has calcium on the anterior mitral leaflet which cannot be removed.
3. Subject has extensive calcification of the aortic root.
4. Annular deformation which may or may not be caused by too extensive decalcification of

the aortic annulus.
5. The position of the coronary ostia relative to the EDWARDS INTUITY Elite Aortic Valve could result in obstruction of blood flow.
6. Minimally Invasive access to the heart is not possible due to anatomical constraints or any other condition (including patient switched to a full sternotomy approach).
7. The device is not available in the correct size for the subject.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-10-2016
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	EDWARDS INTUITY Elite Valve Systems
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	15-09-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-02-2017

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL57530.100.16