Assessing standard oF care and clinical Outcomes UsiNg the EDWARDS INTUITY VAlve SysTem in a European multI-center, active, pOst-market surveillaNce study.

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

Summary

ID

NL-OMON39322

Source
ToetsingOnline

Brief title
FOUNDATION

Condition

- Cardiac valve disorders

Synonym
Aortic Valve Replacement

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Aortic Valve Replacement, Clinical Outcome, Stadard of Care

Outcome measures

Primary outcome

SAFETY ENDPOINTS

• All cause mortality

• Study valve-related mortality

• Hemolysis

• Endocarditis

• Thromboembolic events

• Study valve thrombosis

• All perivalvular leak

• Bleeding events

• Study valve-related reoperation

• Structural valve deterioration of study valve

• Non-structural valve deterioration of study valve

• Study valve explant

• Implant-related new or worsening cardiac conduction disturbance

EFFECTIVENESS ENDPOINTS

• Cross clamp time

• Cardiopulmonary bypass time

• Valve implant time

• Hemodynamic performance: mean gradient, peak gradient, effective orifice area (EOA), EOA index, performance index, cardiac output, cardiac index, valvular regurgitation (including perivalvular leak), end systolic and end diastolic left ventricular volumes confirmed by echocardiography and Core lab evaluation.

• Device technical success defined as the successful delivery and deployment of study valve and delivery system.

• Length of hospital stay

• Length of time in intensive care unit

• Study valve reoperation

• NYHA functional class compared to baseline

• QoL Questionnaire: EQ-5D at baseline and 3 months post procedure

Secondary outcome

Not applicable.

Study description

Background summary

Aortic valve replacement with mechanical or biological heart valves is the treatment of choice for aortic valve stenosis. Over the past several years, life expectancy has increased in industrial nations, but this has been accompanied by a rising rate of elderly patients with multiple illnesses.

Aortic stenosis remains the most common cause of adult valvular heart disease, the prevalence increasing with age. Average survival of patients treated conservatively has historically been reported as 2-5 years from the onset of symptoms. More recent studies have confirmed the dismal prognosis of severe aortic stenosis. Advanced age, reduced left-ventricular ejection fraction,

congestive heart failure and renal insufficiency appear to be independent predictors of reduced survival. Asymptomatic patients with very severe aortic stenosis also share a poor prognosis with a high event rate and a risk of rapid functional deterioration. Early surgery offers a therapeutic option to improve clinical outcomes via decreasing cardiac mortality and improving symptoms Bioprostheses offer several advantages over mechanical bioprostheses, the most important being freedom from anticoagulation with a low rate of thromboembolic accidents.

With increasing patient comorbidity and age, there is a tendency toward biological valve implants avoiding long-term anticoagulation.
Although conventional aortic valve replacement surgery is mostly performed via a full sternotomy surgical approach, minimally invasive aortic valve surgery, since its introduction in 1996, has been gaining acceptance. Several studies have demonstrated reductions in hospital stay, duration of ventilatory support, incisional pain, blood loss and need for blood transfusions in patients undergoing minimally invasive AVR procedures.

In response to clinical need and in support of advances in minimally invasive surgical approaches to conventional AVR, Edwards Lifesciences developed the EDWARDS INTUITY Valve System to achieve clinical benefits by reducing cardiopulmonary bypass and cross clamp times, while facilitating a less invasive approach to aortic valve replacement.
The system includes the EDWARDS INTUITY Valve System, Model 8300A and the EDWARDS INTUITY Delivery System, Model 8300D; the valve is based on prior heart valve designs which have a long history of safety and effectiveness and have incorporated additional features designed to improve patient outcomes and safety.
With only 3 guiding sutures and secure balloon expandable frame, the EDWARDS INTUITY Valve system is well suited for smaller incisions and tight access, with an emphasis on procedural efficiency within existing operating suite of the surgeon.

Study objective

The objectives of this study are to evaluate cardiac performance characteristics and adverse events rates associated with the EDWARDS INTUITY Valve in patients undergoing aortic valve replacement (AVR). The AVR surgical approach is either full or partial sternotomy or through a right anterior thoracotomy.

Study design

The design of this proposed active post-market study is a prospective, single arm, multicenter study.

Intervention

Not Applicable.

Study burden and risks

The potential risks for the study are the same as those for patients undergoing conventional AVR surgery. Key risks are listed below. As with all cardiac surgeries, serious complications, which can lead to death, may be associated with the procedure or use of the products, such as bioprosthetic heart valves and the heart valve replacement procedure. In addition, complications due to individual patient reaction to an implanted device, or to physical or chemical changes in the components, particularly those of biological origin, may occur at varying intervals (hours or days) necessitating reoperation and replacement of the prosthetic device. Risks associated with the use of the devices applicable in the study can be found in the specific products instructions for use (IFU).

Some of the potential risks related to participation in this study are listed below in two categories:
• Risks associated with the surgical aortic valve replacement procedure
• Risks associated with the EDWARDS INTUITY Valve System

Risks associated with surgical replacement of the aortic valve may include but are not limited to the following:
• Allergic reaction
• Anticoagulant related bleeding
• Annular Dissection
• Aortic Dissection
• Arterial Dissection
• Bacteremia
• Bleeding
• Cardiac Arrest
• Cardiogenic Shock
• Deep Vein Thrombosis (DVT)
• Disseminated Intravascular Coagulation (DIC)
• Esophageal rupture
• Heart Failure
• Hemolysis
• Hypotension
• Hypertension
• Infection, local or systemic
• Heparin Induced Thrombocytopenia (HITs)
• Hematoma
• Myocardial Infarction
• Pericardial Effusion

• Pericardial Tamponade
• Peripheral Embolic Event
• Perforation of free myocardial wall
• Pulmonary Embolism
• Pleural effusion
• Procedural bleeding
• Post-procedural bleeding
• Pneumonia
• Sepsis/Septicemia
• Sternal Wound Infection
• Stroke
• Transient Ischemic Attack (TIA)
• Vascular Access Site Complications

In addition to the above, the following are potential risks that could be uniquely associated with the EDWARDS INTUITY Valve System:
• Trauma to the mitral chordae resulting from the delivery system
• Frame damage or under-flaring resulting in a reduction of effective orifice area
• Loss of frame structural integrity resulting in damage to aortic wall or aortic annulus
• Frame expansion resulting in conduction interruptions or disturbances (i.e. arrhythmia)
• Frame expansion resulting in mitral valve impingement or abrasion with or without mitral regurgitation
• Insufficient frame expansion resulting in perivalvular leak requiring

Some or all of these risks may require reoperation, valve explantation, or may lead to permanent disability or death. All events related to the study medical procedure or the valve and any post-operative cardiac related events will be collected and reviewed throughout the study duration and follow-up period. Investigators will be notified of any additional risks identified during the study that could affect the health, safety or welfare of the subjects in the investigation.

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

1. Subject is 18 years or older
2. Subject presents with aortic stenosis or stenosis-based insufficiency of an aortic valve requiring a planned replacement of the native aortic valve or previously implanted aortic prosthesis.
3. Subject has signed and dated the investigation informed consent forms prior to study-specific procedures are performed.
4. Subject is geographically stable and agrees to attend follow-up assessments as specified in the protocol and informed consent.

Exclusion criteria

1. History of active endocarditis within three months of scheduled surgery
2. Subject is diagnosed with pure aortic insufficiency
3. Aneurysm of the aortic root and/or ascending aorta

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2013
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	EDWARDS INTUITY Aortic Valve;Model 8300A
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-04-2013
Application type:	First submission
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	NL41012.060.12