Clinical evaluation of percutaneous implantation of the CoreValve aortic valve prosthesis. Safety and performance study on patients at high risk for surgical valve replacement.

Published: 03-10-2006
Last updated: 21-05-2024

The objectives of the study are to evaluate the performance and safety of percutaneous implantation of the PAV. Primary endpoints will be assessed at discharge and at 30 days (acute benefits), secondary endpoints will be assessed at 3, 6, 12, 24, 36...

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

Summary

ID

NL-OMON29825

Source
ToetsingOnline

Brief title
CoreValve generation 3

Condition

- Cardiac valve disorders

Synonym
aorta valve stenosis, leaking heart valve

Research involving
Human

Sponsors and support

Primary sponsor: CoreValve
Source(s) of monetary or material Support: Corevalve

Intervention

Keyword: aortic-valves, catheterisation, prosthesis, Stenosis

Outcome measures

Primary outcome

· Performance is defined by device functionality based on the

investigator evaluation rating on the system and the procedure success rate at

discharge defined as a correct prosthesis valve function without any major

adverse event (MAE) at discharge (or 10 days whichever occurs first)

· Safety is defined as clinical outcome (composite of MAE including

major adverse cardiac events) at discharge and 30 days.

Secondary outcome

· Clinical : patient functional status (NYHA) from discharge until 48

month follow-up, patient neurological status (NIH stroke scale) from discharge

to 6 month follow-up. MAE from 3 month to 48 month follow-up

· Performance: valve performance , valve migration, paravalvular leak

assessed by Doppler echocardiography from 1 to 48 month follow-up,

Study description

Background summary

This study consists in proposing an alternative to the surgical valve replacement by a mechanical or a biological prosthesis which is today the standard practice of care of heart valve replacement. This alternative to this open-heart surgery is a less invasive using the devices and techniques that allow percutaneous treatment. CoreValve has developed the ReValving System which consists of a bioprosthesis valve mounted and sutured in a self-expanding Nitinol stent. The device is delivered percutaneously via a specific catheter-based technique and implanted within the diseased aortic valve. The new generation ReValving System proposed in this study allows the use of an 18 French delivery catheter and will contribute to increase the ease of valve implantation and decrease the risk of access site complications.

Study objective

The objectives of the study are to evaluate the performance and safety of percutaneous implantation of the PAV. Primary endpoints will be assessed at discharge and at 30 days (acute benefits), secondary endpoints will be assessed at 3, 6, 12, 24, 36 and 48 months follow-up.

Study design

Prospective multicenter single arm safety and performance study by Standard EN-ISO 14155: 2003 part 1&2 on clinical research off medical devices.
Safety en performance are evaluated by discharge and after 30 days. Control of the placement and performance after 3 and 6 months. Long term follow up off the patient after 12, 24, 36 and 48 months.
Interim analysis after 1,3 and 6 months by echo.

Intervention

Via enterance by the arteria femoralis and a single valvuloplasty the delivery catheter with the prosthesis will be implanted over the native aortic valve, by controlled echo and fluoroscopy.

Study burden and risks

Possible risks and discomforts are those which can occur in association with percutaneous implantations and in heart valve surgery: bleeding, hematoma, pain and/or infections at the site of incision, disturbances of heart rhythm, abnormal blood coagulation which may result in blood clots being released into and blocking the blood stream, which in turn can lead to a heart attack or

stroke, torn vessels, unsuitable positioning of the artificial heart valve, incorrect function of the artificial heart valve, need for a repeat intervention, allergy to anesthetics or medications, death.

The expected benefits are due to the fact that no open heart surgery has to be performed and that there will be none of the risks (a usually -temporary- worsening of heart function, infection, lung, kidney or liver problems) and discomforts associated with this type of procedure. A shorter period and an improvement in symptoms and general condition are also expected.

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

significant aortic valve stenosis, euroscore higher than 15 and/or age higher than 75 years

Exclusion criteria

previous aortic valve replacement, recent or evalutive CVA, kreatine clearance less than 20ml per minute, mitral and tricuspid insuffiency more than grade 2

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-10-2006
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	03-10-2006
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-08-2007
Application type:	Amendment

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	23-02-2009
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL12403.078.06