FORWARD PRO Study

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The study purpose is to evaluate the acute and long term clinical performance and safety of the Evolut* PRO System used in routine hospital setting for the treatment of symptomatic native aortic valve stenosis or a stenosed, insufficient, or...

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

Summary

ID

NL-OMON46344

Source
ToetsingOnline

Brief title
FORWARD PRO Study

Condition

- Cardiac valve disorders

Synonym
Aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic Trading NL BV
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: aorticvalve stenosis, TAVI

Outcome measures

Primary outcome

The all-cause mortality rate at 30 days post procedure meets a performance goal of 5.5%.

Secondary outcome

•The percentage of subjects graded as none or trace total aortic regurgitation at discharge is greater than a prespecified performance goal of 67.1%.

•VARC-2 safety and efficacy endpoints as well as hemodynamic performance metrics (incl. mean gradient, effective orifice area and prosthetic regurgitation).

Study description

Background summary

The Evolut* PRO System builds upon the improvements of the Evolut R platform with the added feature of an external pericardial wrap covering the first 1.5 cells of the inflow region. This feature is intended to reduce prosthetic aortic regurgitation. The Evolut* PRO System has completed comprehensive bench testing, and in May of 2016, Medtronic began enrollment in a multi-center clinical study in the United States (US) to confirm the safety and performance of the Evolut* PRO System in high or extreme risk patients with severe symptomatic aortic stenosis. Taken together, these data demonstrate the Evolut* PRO System is safe, performs as intended, and that the benefits outweigh the risks for use in the intended patient population, resulting in CE marking on 28 July 2017.
More background information can be found on page 14-15 of the CIP

Study objective

The study purpose is to evaluate the acute and long term clinical performance and safety of the Evolut* PRO System used in routine hospital setting for the treatment of symptomatic native aortic valve stenosis or a stenosed, insufficient, or combined surgical bioprosthetic valve failure necessitating

valve replacement.

Study design

Prospective, single-arm, multi-center, interventional post-market study.
After signing informed consent, eligible subjects will be implanted with the Evolut* PRO.

Intervention

Main collected data will be:
•Baseline subject demographics, medical history, anatomically eligibility for the CoreValve* Evolut* PRO system, STS-Risk score and Katz ADL
•Procedural/discharge evaluations
•TTE at baseline, discharge, 1-year, 3-year, and 5-year follow-up visit
•12-lead ECG at baseline and discharge
•NYHA at baseline, 30-day, 1-year, 3-years, and 5-year follow-up visit
•Quality of Life assessment at baseline, 30-day, 1-year, 3-year, and 5-year follow-up visit

Study burden and risks

Participation in this study will not exposure the patients to a greater risks than if he/she receiving the CoreValve* Evolut* PRO system, outside of the study.
There might be other discomforts and risks related to CoreValve* Evolut* PRO system or study that are not foreseen at this time.
The risks associated with the CoreValve* Evolut* PRO system are minimized by selecting qualified physicians/ investigators to implant the CoreValve* Evolut* PRO system, selecting an appropriate patient population via inclusion/exclusion criteria and monitoring patient progress and events reported for this study.The review and minimization of the potential risks to the patient and the potential benefits to the patient support the conduct of this study.

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

Patients must meet ALL of the following inclusion criteria:
1.Symptomatic native aortic valve stenosis or a stenosed,
insufficient, or combined surgical bioprosthetic valve failure necessitating valve replacement
2.High or greater risk for surgical aortic valve replacement as estimated by the heart team OR, 75 years or older and at intermediate risk for surgical AVR (STS risk score >=4% or with an estimated hospital mortality >=4% as assessed by the heart team)
3.Acceptable candidate for treatment with the Evolut* PRO system in conformity with the local regulations
4.Able and willing to return to the implanting site at the following follow-up visits: 1-year, 3-year and 5-year
5.Written informed consent obtained without assistance from a legal representative prior to enrollment in the study

Exclusion criteria

Patients are NOT eligible for study participation if they meet ANY of the following exclusion criteria:;1.Known hypersensitivity or contraindication to aspirin, heparin (HIT/HITTS) and bivalirudin, ticlopidine, clopidogrel, Nitinol (Titanium or Nickel), or sensitivity to contrast media, which cannot be adequately premedicated
2.Preexisting mechanical heart valve in aortic position
3.Ongoing sepsis, including active endocarditis
4.Anatomically not suitable for the Evolut* PRO system
5.Estimated life expectancy of less than 1 year

6.Participating in another trial that may influence the outcome of this study
7.Need for emergency surgery for any reason
8.Inability to understand and respond to the quality of life questionnaire

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):	02-05-2018
Enrollment:	180
Type:	Actual

Medical products/devices used

Generic name:	CoreValve Evolut PRO System (Evolut PRO System)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-03-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	24-07-2018
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
ClinicalTrials.gov	NCT03417011
CCMO	NL64028.100.17