PROVE ACURATE neo2TM - post market safety and performance surveillance in aortic stenosis

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To further evaluate the safety, efficacy and device performance of the ACURATE neo2* aortic bioprosthesis and ACURATE neo2* transfemoral delivery system in 2000 consecutive patients with severe aortic stenosis according to VARC-3 criteria.

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

Summary

ID

NL-OMON56524

Source
ToetsingOnline

Brief title
PROVE

Condition

- Cardiac valve disorders

Synonym
Severe aortic stenosis, severe narrowing of the aortic valve

Research involving
Human

Sponsors and support

Primary sponsor: Leipzig University
Source(s) of monetary or material Support: BOSTON SCIENTIFIC INTERNATIONAL S.A.

Intervention

Keyword: Aortic bioprosthesis, efficacy and device, performance, Safety, Severe aortic stenosis, TAVI

Outcome measures

Primary outcome

All-cause mortality up to 12 months follow-up.

Secondary outcome

- Clinical endpoints according to VARC-3 at the respective time points:

mortality, neurologic events, myocardial infarction, re-hospitalization,

bleeding and transfusions, vascular and access-related complications, cardiac

structural complications, other procedural or valve-related complications, new

conduction disturbance and arrhythmia, acute kidney injury, bioprosthetic valve

dysfunction, clinically significant valve thrombosis, and patient-reported

outcomes and health status (Kansas City Cardiomyopathy Questionnaire)

- Technical success at exit from procedure room (VARC-3)

- Device success at 30 days (VARC-3)

- Early safety at 30 days (VARC-3)

- Clinical efficacy at 12 months (VARC-3)

- Change of hemodynamic function (effective orifice area and mean

transprosthetic gradient) post-procedure at hospital discharge, 30 days and 12

months

- Moderate or severe haemodynamic valve deterioration after 12 months

- Moderate and severe prosthesis-patient mismatch at hospital discharge

- Total aortic regurgitation post-procedure at hospital discharge and 12 months

- Bioprosthetic valve failure at hospital discharge and at 12 months

Study description

Background summary

Over the last two decades, TAVI has become an essential treatment option for patients with severe aortic valve stenosis. This technique treats aortic stenosis by displacing and functionally replacing the native valve with a bioprosthetic valve delivered on a catheter. The ACURATE neo bioprosthetic aortic valve is one of several transcatheter heart valve (THV) designs available for transfemoral TAVI. The key features of this self-expanding THV are a supra-annular design and porcine pericardial leaflets. A further characteristic is a topdown deployment as well as three stabilization arches and an upper crown.

Study objective

To further evaluate the safety, efficacy and device performance of the ACURATE neo2* aortic bioprosthesis and ACURATE neo2* transfemoral delivery system in 2000 consecutive patients with severe aortic stenosis according to VARC-3 criteria.

Study design

Single arm, multicenter, prospective, observational study with embedded substudies.

Study burden and risks

There are no risks to subjects associated with participation in the study and the burden is minimal for subjects when participating in the 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

1. Planned transcatheter treatment of severe aortic stenosis with the ACURATE neo2 aortic bioprosthesis and ACURATE neo2 transfemoral delivery system. 2. Age >= 18 years of age. 3. Written informed consent by patient and/or legal representative.

Exclusion criteria

1. Patient is unlikely to be able or willing to follow the investigator's instructions during study
participation.
2. Patients temporally unable to provide written informed consent (e. g. unconscious
emergency patients).
3. Patients placed in an institution by official or court order.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-12-2023
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	ACURATE neo2 Aortic Valve / Transfemoral Delivery System
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-02-2024
Application type:	First submission
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
Other	NCT05539573
CCMO	NL83969.078.23