ACURATE neo2 PMCF: ACURATE neo2* (S2410): Post Market Clinical Follow-up Study

Published: 16-12-2020
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To collect clinical and device performance outcomes data with the ACURATE neo2* Transfemoral Aortic Valve System as used inroutine clinical practice for the treatment of severe calcific aortic stenosis.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON52458

Source
ToetsingOnline

Brief title
ACURATE neo2 (S2410)

Condition

- Other condition
- Cardiac valve disorders

Synonym
aortic valve stenosis

Health condition

severe native aortic valve stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific International SAS
Source(s) of monetary or material Support: Boston Scientific

Intervention

Keyword: aortic valve, severe, stenosis, symptomatic

Outcome measures

Primary outcome

Primary Safety Endpoint: All-cause mortality at 30 days after the index implant

procedure.

Primary Imaging Endpoint: Hypoattenuated leaflet thickening (HALT) as measured

by 4D CT at 30 days

Secondary outcome

Additional measurements based on the Valve Academic Research Consortiuma (VARC)

endpoints and definitions will be collected

peri- and post-procedure, at pre-discharge, at 30 days, and annually 1 through

5 years after the implant procedure, unless otherwise

specified: see protocol ACURATE neo2 PMCF Study-Specific Protocol 92383173

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Study description

Background summary

Severe aortic valve stenosis is the narrowing of one of the heart*s major valve. This narrowing reduces the amount of blood that can get to the body. Severe aortic valve stenosis is caused by calcification of the heart valve leaflets (tissue that opens and closes in the heart valve) so that the valve cannot work properly. If left untreated, excessive strain put on the heart

muscle will eventually cause it to fail or lead to other serious complications. ACURATE neo2 Aortic Valve System is intended to be used to treat this symptoms and restore a normal functionality of your heart. The device received CE marked in April 2020 and the objective of this study is to evaluate the safety performance of ACURATE neo2 Aortic valve.

Study objective

To collect clinical and device performance outcomes data with the ACURATE neo2* Transfemoral Aortic Valve System as used in
routine clinical practice for the treatment of severe calcific aortic stenosis.

Study design

ACURATE neo2 PMCF is a prospective, open-label, single-arm, multicenter, observational post-market surveillance study. All
subjects deemed treatable with the ACURATE neo2 valve will be approached to participate in the study. A subject who provides an Informed Consent Form (ICF) approved by the Ethics Committee and signed by the subject or the subject*s legally authorized representative is considered enrolled once an attempt is made to insert the commercially available ACURATE neo2 Transfemoral Delivery System. Approximately 200 subjects will be enrolled.
Follow-up will occur at pre-discharge, 30 days, 1 year, and then annually from 2 through 5 years post index procedure per standard of care. Visits are in-person through 1 year and in-person (preferred) or via telephone interview in years 2 through 5. All subjects will undergo 4D computed tomography (CT) imaging at 30 days and 1 year. Subjects who are enrolled but not implanted with an ACURATE neo2 valve in the aortic position will be followed for safety through 30 days after the initial attempted index procedure but will not undergo 4D CT imaging. Subjects who require a second transcatheter valve (valve-in-valve) or conversion to surgery during the index procedure will be followed for safety through 1 year but will not undergo 4D CT imaging.

Study burden and risks

The patient may or may not receive any benefit from participating in this study. However, medical science and future subjects may benefit from your participation. It is possible that the collection of information on the effectiveness and safety of the device will allow early detection of unforeseen problems.

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

There are no specific inclusion criteria set for this post-market surveillance study. A subject must sign an IEC/REB-approved ICF and the ACURATE neo2 Transfemoral Aortic Valve System should be used according to the commercial IFU.

Exclusion criteria

EC1. Subject has a previous bioprosthesis in the aortic position.
EC2. Subject has eGFR <30 mL/min (chronic kidney disease stage IV or stage V).
EC3. Subject has atrial fibrillation that cannot be rate controlled to ventricular response rate < 60 bpm.
EC4. Subject is expected to undergo chronic anticoagulation therapy after the TAVI procedure.
Note: Subjects treated with short-term anticoagulation post-procedure can be included in the study; in these subjects the 30-day imaging will be performed

30 days after discontinuation of anticoagulation.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2021
Enrollment:	65
Type:	Actual

Medical products/devices used

Generic name:	Commercially available ACURATE neo2 Transfemoral Aortic Valve System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-12-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-12-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	26-07-2023
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
ClinicalTrials.gov	NCT04655248
CCMO	NL74565.078.20