ACURATE TA* Transapical Aortic Bioprosthesis for Implantation in Patients with Severe Aortic Stenosis

Published: 25-04-2012
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Primary: To evaluate the safety of the study device in patients presenting with severe aortic stenosis (AS) considered to be high risk for surgery.Secondary: To evaluate adverse events and study device performance.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON37451

Source
ToetsingOnline

Brief title
2011-01 ACURATE TA*

Condition

- Cardiac disorders, signs and symptoms NEC
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Severe Aortic Stenosis

Research involving
Human

Sponsors and support

Primary sponsor: SYMETIS S.A.
Source(s) of monetary or material Support: SYMETIS S.A.

Intervention

Keyword: ACURATE TA, Aortic Stenosis, Implantation, Transapical

Outcome measures

Primary outcome

Primary: Freedom from all-cause mortality at 30 days follow-up

Secondary outcome

Secondary:

1. Rate of major cardiac and cerebrovascular event (MACCE) at 30

days and at 12 months

2. Functional improvement from baseline as per NYHA functional

classification at 30 days and at 12 months

3. Procedural success post-implant

4. Device success at 30 days and at 12 months

Study description

Background summary

The patient will be asked to participate in the investigational study because the patient suffers from severe aortic stenosis.

Study objective

Primary: To evaluate the safety of the study device in patients presenting with severe aortic stenosis (AS) considered to be high risk for surgery.
Secondary: To evaluate adverse events and study device performance.

Study design

- A single arm, prospective, multicenter, non-randomized and open trial;
- 150 implanted patients at up to 15 European sites.

Intervention

-

Study burden and risks

-

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. Patients 70 years of age and older
2. Additive EuroSCORE * 9

3. Severe aortic stenosis characterized by mean aortic gradient > 40 mmHg or peak jet velocity > 4.0 m/s or aortic valve area of *1.0 cm2
4. NYHA Functional Class > II
5. Aortic annulus diameter from * 21mm up to * 27mm by TEE
6. Patient willing to participate in the study and provides signed informed consent

Exclusion criteria

1. Congenital unicuspid or bicuspid aortic valve
2. Severe eccentricity of calcification
3. Severe mitral regurgitation (> 2°)
4. Pre-existing prosthetic heart valve in any position and / or prosthetic ring
5. Severe transapical access problem, non-reachable LV apex
6. Previous surgery of the LV using a patch, such as the Dor procedure
7. Presence of apical LV thrombus
8. ECHO evidence of intracardiac mass, thrombus, or vegetation
9. AMI within 1 month prior to the procedure
10. PCI within 1 month prior to the procedure
11. Previous TIA or stroke in the last 3 months
12. Untreated coronary artery disease (CAD) requiring revascularization
13. Hemodynamic instability: systolic pressure <90mmHg without afterload reduction, shock, need for inotropic medication or IABP
14. LVEF < 30% by ECHO
15. Calcified pericardium
16. Septal hypertrophy unacceptable for transapical procedure
17. Primary hypertrophic obstructive cardiomyopathy (HOCM)
18. Active infection, endocarditis or pyrexia
19. Active peptic ulcer or gastrointestinal (GI) bleeding within the past 3 months
20. Liver failure
21. Severe COPD requiring home oxygen
22. Blood dyscrasias: leukopenia (WBC < 3000mm3), acute anemia (Hb < 9 mg%), thrombocytopenia (platelet count < 50,000 cells/mm3), history of bleeding diathesis or coagulopathy
23. Chronic renal dysfunction with serum creatinine > 2.5 mg/dL or renal dialysis
24. Neurological disease severely affecting ambulation or daily functioning
25. Senile dementia
26. Another surgical or percutaneous procedure scheduled at the same time
27. Emergency procedure pre-implant
28. Life expectancy < 12 months due to non-cardiac co-morbid conditions
29. Known hypersensitivity/contraindication to study medication, contrast media, or nitinol
30. Currently participating in an investigational drug or another device study

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	ACURATE TA Transapical Aortic Bioprosthesis and ACURATE TA Transapical Delivery System
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	25-04-2012
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	France (AFSSAPS): 2011-A00838-38
CCMO	NL37774.068.11