ATS 3f Enable* Aortic Bioprosthesis pivotal study

Published: 24-10-2008
Last updated: 07-05-2024

To evaluate the safety and effectiveness of the ATS 3f Enable* Aortic Bioprosthesis equine pericardial stented bioprosthesis in a patient population undergoing isolated aortic valve replacement with or without concomitant procedures.

Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac valve disorders
Study type	Interventional

Summary

ID

NL-OMON32374

Source
ToetsingOnline

Brief title
ATS 3f Enable* Aortic Bioprosthesis

Condition

- Cardiac valve disorders
- Cardiac therapeutic procedures

Synonym
aortic valve replacement, cardiac valve prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: ATS Medical Inc.
Source(s) of monetary or material Support: ATS Medical Inc.

Intervention

Keyword: Aortic valve, Nitinol stent

Outcome measures

Primary outcome

The primary effectiveness endpoints will be determined by the New York Heart Association (NYHA) functional classification by comparing baseline (preoperatively) to each postoperative assessment. Additionally, NYHA functional classification data will be compared to data for other similar valves (stented bioprosthetic valves) published in articles in the prosthetic heart valve literature.

Hemodynamic performance of the implanted valve will be evaluated at each postoperative assessment.

The primary safety endpoints for the study are valve migration, valvular thrombosis, valve related thromboembolism, hemorrhage (all and major), perivalvular leak (all and major), endocarditis, hemolysis, structural valve deterioration, nonstructural dysfunction, reoperation, explant, and death (all and valve related).

Secondary outcome

Long term safety endpoints will be compared to twice the Objective Performance Criteria (OPC) events as is standard for prosthetic heart valve studies.

Study description

Background summary

ATS Medical Inc. has developed an aortic heart valve (ATS 3f Enable* Aortic Bioprosthesis) designed to increase patient safety by reducing the duration of cardiopulmonary bypass and cross-clamp time during surgery, through the reduction of the time required to implant the valve.

Study objective

To evaluate the safety and effectiveness of the ATS 3f Enable* Aortic Bioprosthesis equine pericardial stented bioprosthesis in a patient population undergoing isolated aortic valve replacement with or without concomitant procedures.

Study design

A prospective, non-randomized, multi-center study designed to evaluate safety and effectiveness of the device using a common clinical protocol.

Intervention

The ATS 3f Enable* Aortic Bioprosthesis was developed for aortic valve replacement.
The ENABLE bioprosthesis is supplied sterile. A polyacetal homopolymer folding sleeve is attached to the bioprosthesis and is used in conjunction with an accessory inserter system to aid in folding and inserting of the bioprosthesis.

Study burden and risks

General surgical risks may include but are not limited to: anesthesia complications, drug reactions, infection/inflammation which can lead to endocarditis, pain and discomfort or bleeding at the incision site or chest drainage tube insertion site.
The primary risk associated with prosthetic heart valve replacement is failure to restore heart valve function. All prosthetic heart valve implants carry risks of serious complications and/or death related to unacceptable hemodynamics, durability, valvular thrombosis, thromboembolism, hemorrhage, endocarditis, perivalvular leak, hemolysis, valvular pannus, nonstructural dysfunction, structural valve deterioration, reoperation, explantation, arrhythmia, heart failure, angina, myocardial infarction, stroke, and death.[1] Risks may also include calcification of the prosthetic valve leaflets and transmission of virus. In addition, risks specific to this ATS 3f Enable* Aortic Bioprosthesis may include valve migration (movement of the valve from its original locus), tilting, distortion, stent failure (fracture or corrosion), or perforation of the aorta due to stent post.
The primary benefit is restoration of heart blood flow control by replacement of the diseased heart valve. In addition, since the primary implantation of this valve is limited to a guiding stitch, it is expected that a patient

receiving this device may require shorter exposure to the risks of cardiopulmonary bypass or Heart/Lung Machine (HLM) than a similar patient receiving a commercially available bioprosthetic valve.

Contacts

Public
ATS Medical Inc.

3905 Annapolis Ln., Ste.105
Plymouth, MN 55447
USA
Scientific
ATS Medical Inc.

3905 Annapolis Ln., Ste.105
Plymouth, MN 55447
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Preoperative Inclusion Criteria
1. This patient requires isolated aortic valve replacement with or without concomitant procedures such as coronary artery bypass or another valve repair. (The three remaining valves must be of native tissue).
2. This patient is geographically stable and willing to return to the implant site for follow-up visits.
3. This patient has been adequately informed of risks and requirements and consents to

his/her participation in the clinical study.
4. If this patient is female and of childbearing potential, patient has a negative pregnancy test within seven (7) days prior to the study procedure.

Exclusion criteria

Preoperative Exclusion Criteria
1. This patient requires replacement of two or more valves.
2. This patient is < 20 years of age.
3. This patient has a non-cardiac major or progressive disease, which in the Investigator*s experience produces an unacceptable increased risk to the patient, or results in a life expectancy of less than 24 months.
4. This patient is an intravenous drug and/or alcohol abuser.
5. This patient presents with active endocarditis or other systemic infection.
6. This patient has had previous valve replacement surgery, including previous implant and then explant of the ATS 3f Enable* Aortic Bioprosthesis (Model 6000) or placement of a rigid annuloplasty ring in the mitral position.
7. This patient is participating in concomitant research studies of investigational products.
8. This patient presents with dilatation of the ascending aorta, Marfan Syndrome, Ehlers-Danlos syndrome, cystic medial degeneration, or other condition causing the ascending aorta to be irregular in geometry or physiology as seen via preoperative imaging.
9. This patient has chronic renal failure. ;Preoperative Exclusion Criterion for Single Guiding Suture Technique
1. Since this protocol stipulates that the study valve must be fully sutured in place (using standard valve suture placement technique) or abandoned at implant if the patient presents with fused or non-fused bicuspid valve or irregular annular geometry, any patient with fused or non-fused bicuspid valve or irregular annular geometry will be excluded if Investigator elects not to fully suture the valve in place. ;Intraoperative Exclusion Criteria
1. This patient presents with abnormal geometry of the coronary ostia, not seen by preoperative imaging, which presents a risk that the study device may occlude one or all ostia.
2. This patient presents with dilatation of the ascending aorta, Marfan Syndrome, Ehlers-Danlos syndrome, cystic medial degeneration, or other condition causing the ascending aorta to be irregular in geometry or physiology not seen in preoperative imaging.
3. This patient has or requires treatment with a rigid annuloplasty ring in the mitral position at the time of the procedure.
4. This patient presents with active endocarditis not detected preoperatively.;Intraoperative Exclusion Criteria for Single Guiding Suture Technique
1. This patient presents with fused or non-fused bicuspid valve or irregular annular geometry not seen in preoperative imaging and Investigator elects not to fully suture the valve in place. Note: This protocol allows Investigator to implant the study device using standard valve suture placement in patients with fused or non-fused bicuspid valve or irregular annular geometry.
2. After debriding the annulus, the operating surgeon determines that this patient has residual calcification that would not provide optimal fit for the study device.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	ATS 3F EnableTM Aortic Bioprosthesis
Registration:	No

Ethics review

Not approved

Date:	24-10-2008
Application type:	First submission
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
Other	DE/CA25/00004193-00
CCMO	NL22067.100.08