Pivotal Study Of A Dual Epicardial & Endocardial Procedure (DEEP) Approach for Treatment of Subjects with Persistent or Long Standing Persistent Atrial Fibrillation with Radiofrequency Ablation

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The objective of this study is to establish the safety and effectiveness of a dual epicardial and endocardial ablation procedure for patients presentingwith Persistent Atrial Fibrillation or Longstanding Persistent Atrial Fibrillation utilizing the...

Ethical review	Approved WMO
Status	Suspended
Health condition type	Cardiac arrhythmias
Study type	Interventional

Summary

ID

NL-OMON47579

Source
ToetsingOnline

Brief title
DEEP Pivotal Study

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, fibrillation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Catheter Ablation, Persistent AF, Radiofrequency ablation, Surgical Ablation

Outcome measures

Primary outcome

The primary effectiveness endpoint is freedom from any documented AF, atrial flutter, or atrial tachycardia lasting >30 seconds duration through the 12 month follow-up visit in the absence of Class I or III AADs (with the exception of previously failed AADs at doses not exceeding those previously failed).

The primary safety endpoint is a composite endpoint consisting of any one or more of the following events if they are adjudicated by the CEC to be serious adverse events (SAEs) and related to device/procedures as follows:
1. the AtriCure Bipolar System, the AtriClip PRO 1 or PRO2 LAA Exclusion System, within 30 days of the epicardial surgical ablation procedure, or
2. The epicardial surgical ablation procedure within 30 days following the epicardial procedure; or
3. The endocardial index procedure (or a repeat endocardial ablation procedure performed during the blanking period) within 7 days following an endocardial ablation procedure.

Events except as otherwise specified for a particular condition include:

a. death (regardless of cause)

b. stroke

c. transient ischemic attack (TIA)

d. myocardial infarction (MI)

e. pulmonary or systemic embolism

f. pericarditis resulting in an effusion that leads to hemodynamic compromise or requires pericardiocentesis, prolongs hospitalization by more than 48 hours, requires a new hospitalization, or persists for more than 30 days following the ablation procedure

g. excessive bleeding, defined as one or more of the following:

i. re-operation to control bleeding within 7 days post-epicardial surgical procedure; or surgery to control bleeding within 7 days post-endocardial ablation procedure, if related to the endocardial catheter ablation

ii. receipt of >= 2 units of blood transfused in a 24 hour period during the first 7 days post-epicardial surgical procedure; or within the first 7 days postendocardial ablation procedure, if related to the device or procedure

iii. conversion to sternotomy or thoracotomy that requires >= 2 units blood to be transfused, or performed to treat hypotension, cardiac arrest, or repair of a cardiac injury

h. wound infection at surgical site requiring re-operation for wound debridement

i. atrio-esophageal fistula (from the time of surgical procedure through 12 month follow-up visit)

j. permanent phrenic nerve paralysis, defined as paralysis that remains unresolved at the 12 month follow-up visit

k. permanent pacemaker implantation that is a direct result of injury to the specialized conduction system (SA node or AV node) during the epicardial surgical ablation procedure

l. pulmonary vein (PV) stenosis of >70%, as measured at any time after the catheter ablation procedure through the 12 month follow-up visit

m. major vascular access complications, including development of a hematoma, an arteriovenous fistula, or pseudoaneurysm that requires surgical repair or transfusion, prolong hospital stay, or require a new hospital admission

Secondary outcome

Seconday safety endpoints

1. Exclusion of the LAA, defined as defined by lack of fluid communication (<3 mm residual communication with LAA and < 10mm residual pocket) between the LA and LAA. This endpoint will be measured at the 3 Month Visit (Visit 9). The AtriClip effectiveness population will be utilized for this analysis endpoint.

2. Exclusion of the LAA, defined as lack of fluid communication (<3 mm residual communication with LAA and <10 mm residual pocket) between the LA and LAA. The endpoint will be measured intra-procedurally (Visit 2), at the Endocardial EP Ablation Procedure (Visit 5) and at the 12 Month Visit (visit 11). The AtriClip effectiveness population will be utilized for this analysis endpoint.

3. Acute procedural success of epicardial surgical procedure, defined as the percentage of subjects with successful electrical isolation/block of all pulmonary veins, as well as the *box.*

4. Acute procedural success of endocardial catheter procedure, defined as the percentage of subjects with successful electrical isolation/block of all

pulmonary veins and the *box*, as well as bi-directional block of the cavo-tricuspid isthmus.

5. Freedom from Atrial Fibrillation, Atrial Tachycardia, Atrial Flutter without AAD, defined as no documented event >30 seconds in duration (or for the entire length of an ECG tracing) with no utilization of AADs beyond the blanking and AAD optimization periods, except as previously failed without an increase in dose. This endpoint will be measured through the 12 month, 2, 3, 4, and 5 year visits (Visits 11-15) via continuous 24-hour ECG monitor.

6. Freedom from Atrial Fibrillation, Atrial Tachycardia, Atrial Flutter regardless of AAD, defined as no documented event >30 seconds in duration (or for the entire length of a 30 second ECG tracing) regardless of AAD usage. This endpoint will be measured through the 12 month, 2, 3, 4, and 5 year visits (Visits 11-15 via cumulative 24-hour ECG monitoring).

7. Freedom from any documented Atrial Fibrillation, atrial flutter, or atrial tachycardia lasting >10 minutes in duration through the 12 month follow-up visit in the absence of Class I or III AADs (with the exception of previously failed AADs at doses not exceeding those previously failed).

8. Incidence of stroke or TIA at 12, 24, 36, 48, 60 month visits.

9. Change in Quality of Life, defined as the total AFEQT score measured at the 12 month follow-up visit minus the score at the baseline visit. The score will be calculated per the AFEQT scoring manual.

All secondary safety endpoints are supplemental and intended to provide a more

complete safety profile for the DEEP procedure. These endpoints will not be tested for labeling purposes.

1. Major surgical events - This will be a composite safety endpoint within 30 days of the epicardial surgical procedure, as otherwise defined in the primary safety endpoint.

2. Major catheter events - This will be a composite safety endpoint within 7 days of the endocardial catheter procedure, as otherwise defined in the primary safety endpoint.

3. 30 day surgical SAEs - This will include all SAEs that occur within 30 days of the epicardial surgical procedure and that are adjudicated to be related to the device or to the procedure.

4. 12 month DEEP SAEs - This will include all SAEs through the 12 month follow-up visit that are adjudicated to be related to an AtriCure device or to either stage of the DEEP procedure.

5. Unresolved SAEs - This will include all SAEs through the 12 month follow-up visit that are adjudicated to be related to an AtriCure device or to either stage of the DEEP procedure and that are not fully resolved by the 12 months visit. These events shall include any procedure-related deaths, strokes with residual disability, unresolved phrenic nerve damage, or other such events that are adjudicated to have resulted in chronic disability or permanent damage.

6. Any serious adverse event through the 12 month follow-up visit, regardless of attribution.

Study description

Background summary

The proposed staged epicardial and endocardial approach with the AtriCure*s Bipolar System is being developed to improve on the efficacy in the treatment of Persistent and Longstanding Persistent AF patients which currently represents a group of patients with less effective treatment alternatives.

Study objective

The objective of this study is to establish the safety and effectiveness of a dual epicardial and endocardial ablation procedure for patients presenting with Persistent Atrial Fibrillation or Longstanding Persistent Atrial Fibrillation utilizing the AtriCure Bipolar System and AtriClip® PRO 1 or PRO2 LAA Exclusion System in an endoscopic or open ablation procedure, followed by an endocardial mapping and ablation procedure utilizing commercially available RF based, irrigated, power controlled, ablation catheters for endocardial lesions. The following catheters are approved for use in the left atrium:
• BioSense Webster ThermoCool (Navistar Thermocool Catheter, BioSense Webster WZ Steer Thermocool Catheter Nav Thermocool SF Catheters or BioSense Webster Thermocool SmartTouch)
• St Jude TactiCath Quartz Catheter and the FlexAbility Catheter.
The endocardial procedure will be staged to occur after 90 days post epicardial surgical procedure.

Study design

This is a prospective, multi-center, single arm, pivotal study to establish the safety and effectiveness of a staged epicardial and endocardial ablation procedure utilizing the AtriCure Bipolar System and AtriClip® PRO1 or PRO2.

Up to 220 patients will take part in this trial in up to 25 sites. it is expected that each site will enroll approximately 10 patients. The trial will take approximately 12.5 years in total. An enrollment period of 7.5 years is expected followed by a 5 year follow up period.

Intervention

A dual epicardial and endocardial radiofrequency ablation procedure for patients presenting with Persistent Atrial Fibrillation or Longstanding Persistent Atrial Fibrillation.

Study burden and risks

This study is being undertaken to examine the safety and efficacy of minimally invasive surgical staged procedure when used in patients with persistent or longstanding persistent atrial fibrillation. Subjects meeting the inclusion/exclusion criteria for this study are indicated for interventional treatment for atrial fibrillation. Ablation procedures are commonly performed and are a well-accepted treatment for subjects with AF, with a well-established risk profile. Risks to subjects undergoing minimally invasive ablation surgery and epicardial procedures are listed below. The risks of participation are offset by the significant potential for clinical and functional benefits to subjects with AF that comes through restoring heart rhythm.
The potential benefit to study subjects outweighs the risks of participation in this study. The benefits may include but are not limited to the following:
- Clinical improvement
- Functional improvement
- Overall advancement of medical and scientific knowledge that may benefit future patients with similar conditions may be gained through this clinical study. There may also be other benefits that are unforeseen at this time.
Adverse events that may be anticipated in this clinical study are believed to be consistent with those associated with other minimally invasive surgical and catheter-based EP procedures. Complications may occur at any time during the procedures, post-procedures or follow up period.
The clinical study is justified because the clinical investigators and the Sponsor believe the potential benefits outweigh the potential risks.

Contacts

Public
Atricure Inc.

Innovation Way 7555
Mason, OH 45040
US
Scientific
Atricure Inc.

Innovation Way 7555
Mason, OH 45040
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with symptomatic (e.g. palpitations, shortness of breath, fatigue) Persistent Atrial Fibrillation or Longstanding Persistent Atrial Fibrillation refractory to a minimum of one Class I or Class III AADs.

Exclusion criteria

Patient has undergone prior cardiothoracic surgery (lungs or mediastinum).
Patient has NYHA Class IV heart failure.
Patient has an ejection fraction < 30% (based on baseline transthoracic echocardiography or equivalent diagnostic test).
Patient has evidence of underlying Coronary Artery Disease requiring intervention (either surgical, i.e. CABG, or catheter).

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	15-02-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Staged epicardial and endocardial approach for treatment of persistent atrial fibrillation with radi
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	29-10-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-02-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NCT02393885
CCMO	NL53049.018.15