European Multicenter Registry using Hybrid Staged Operating Room and Interventional Catheter Ablation Techniques to treat Chonic Atrial Fibrilation "HISTORIC-AF Registry"

Published: 06-11-2013
Last updated: 23-04-2024

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Ethical review	Not approved
Status	Will not start
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON38534

Source
ToetsingOnline

Brief title
HISTORIC-AF Registry

Condition

- Cardiac arrhythmias

Synonym
Atrial Fibrilation, disorder of the Atrail Rhythm

Research involving
Human

Sponsors and support

Primary sponsor: Amphia Ziekenhuis
Source(s) of monetary or material Support: Esetch Inc, San Ramon California USA,Estech Inc.

Intervention

Keyword: Chronic Atrial Fibrilation, Minimally invasive surgical abaltion, Optional EP intervention, Prospective registry

Outcome measures

Primary outcome

The primary efficacy endpoint is the rate of therapeutic success of thoracoscopic surgical ablation, with a target rate of > 60%. Surgical ablation success is defined as freedom from AF without the need for EP ablation, during 12 months after surgery, based on 24-hour Holter monitor results, and freedom from AADs beginning at 6 months following surgery. Arrhytmias during the blanking period (first 3 months after ablation) are excluded from evaluation.

The primary safety endpoint is a composite safety endpoint consisting of the incidence of the following early onset serious adverse events (SAEs) (i.e., within 30 days of the last RF ablation procedure) including all cause death, stroke and TIA, myocardial infarction, thromboembolic events, bleeding, access site infection, need for permanent pacemaker, pulmonary vein stenosis, esophageal fistula, cardiac tamponade or pericardial effusion requiring intervention.

Secondary outcome

Not Applicable

Study description

Background summary

AF currently affects approximately 2.2 million patients in the U.S. and is the most common rhythm disorder among U.S. patients hospitalized with a primary diagnosis of an arrhythmia The increased rates of morbidity and mortality associated with AF demonstrate the need for an effective and reliable treatment for AF. Additionally, the increased survival rates observed in mitral valve repair patients who were previously suffering from AF suggest that restoring NSR is associated with improved patient outcome.
Anti-arrhythmic drug (AAD) therapy remains the first line of treatment for AF; however, it does not represent a cure for AF. All AAD therapies used for AF treatment have significant side effects and they are of marginal effectiveness in nearly all patient populations. Atrial pacing and defibrillators do not cure the arrhythmia and may not result in better quality of life.
RF catheter ablation with creation of complex and extensive lesions in the left atrium has resulted in variable rates of success in patients suffering from persistent AF, but this can only be achieved with long procedure times and extended fluoroscopy exposure for patients and medical staff.
As an alternative, an open heart Cox Maze procedure may be used to eliminate AF by creating incisional scars to block abnormal electrical circuits that maintain the arrhythmia. Success rates at 1 year are approximately 70% for persistent AF and 80% for paroxysmal AF.

Study objective

The objective of the study is to demonstrate that the creation of cardiac lesions with epicardially applied RF ablation through a minimally invasive surgical (MIS) approach plus EP ablation performed when needed at least 3 months later enhances the efficacy of the treatment for persistent AF.

Study design

Prospective, multi-center, investigator-driven registry that will include patients with a history of chronic AF who require thoracoscopic surgical ablation due to clinical indications (corresponding to the study inclusion criteria)..
This study hypothesizes that combining surgical endoscopic and transcatheter techniques in a staged fashion provides superior clinical outcomes to isolated surgical or EP approaches in patients with persistent AF lasting > 1 year but <5 years.The surgical ablation procedure involves the creation of cardiac

lesions with epicardially applied radiofrequency (RF) ablation through a minimally invasive surgical (MIS) approach. This procedure is performed according to standard of care techniques for thoracoscopic ablation.
A delayed EP ablation procedure will be performed when needed after thethe surgical ablation, according to the indications specified in the current scientific consensus (2012 Guidelines*):
• Repeat ablation with an EP procedure is indicated in patients with recurrence of AF after the index surgery. Since early recurrences of AF and/or the development of atrial tachyarrythmias is common during the first two to three months after AF ablation and may resolve spontaneously, the EP ablation will be deferred for at least three months (blanking period) following the initial surgical procedure; with the exception of patients who develop highly symptomatic atrial arrhythmias that cannot be controlled with antiarrhythmic therapy or slowed with rate controlling medications, who are best managed with a reablation procedure within the first three months post surgical AF ablation.
• In addition, repeat EP ablation is recommended in patients who develop left atrial flutter or tachycardia following surgical AF ablation; many of these patients are highly symptomatic and their ventricular rate is difficult to control, making the performance of another ablation procedure mandatory.

*2012 HRS/EHRA/ECAS Expert Consensus Statement on Catheter and Surgical Ablation of Atrial Fibrillation. Heart Rhythm, Vol 9, No 4, April 2012

Study burden and risks

All patients will be treated with state-of-the-art procedures using approved CE-marked devices and techniques. The use of thoracoscopic ablation is known to be safe and effective when used for the approved indications. The EP diagnostic and ablation procedure and follow-up activities will be carried out in accordance with approved diagnostic techniques and standard operating procedures for the centers. Therefore, enrollment in this registry does not pose undue risks to the patients. Because this study limits enrollment and is being performed under a closely controlled protocol, the possible benefits anticipated with the treatment administered far outweigh the potential 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

Symptomatic Recurrent Persistent AF or Long Standing Persistent AF, for > 1 year and < 5 years.
Documented effectiveness failure of at least one Class I or III AAD
Absence of LA thrombus by TEE, CT scan, MRI or angiography
Age 18-75 years
Written informed consent

Exclusion criteria

Documented left atrial size greater than 55 mm.
Documented LVEF of 40% or less.
History of cerebrovascular disease, including stroke or TIA within 6 months prior to enrollment
Previous heart surgery
COPD (70% predictive lung function)
Contraindication to anticaogulant therapy, or inability to comply with anticoagulation therapy
Pregnancy, planned pregnancy or breastfeeding
Concomitant cardiac surgery procedure planned.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Minimally invasive surgical ablation with COBRA Fusion system within the standard of care
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	06-11-2013
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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
CCMO	NL46038.015.13