A Prospective, Multicenter, Investigation of the Adagio Cryoablation System in Patients with Atrial Fibrillation (AF).

Published: 29-08-2016
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The objective of the study is to demonstrate the safety and performance of the Adagio Cryoablation System in patients with paroxysmale (PAF), persistent or Long-Standing Persistent Atrial Fibrillation.

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

Summary

ID

NL-OMON47348

Source
ToetsingOnline

Brief title
CryoCure2

Condition

- Cardiac arrhythmias

Synonym
Abnormal heart rhythm, Atrial Fibrillation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atrial Fibrillation, Cryo-ablation

Outcome measures

Primary outcome

Safety: The primary safety endpoint will be determined by evaluating:

• the incidence of procedural adverse events

• the incidence of serious adverse events within 7 days of procedure, > 7 days, and > 30 days

Performance: Technical performance assessed by:

• complete electrical isolation of all pulmonary veins (entrance block)

• AF termination targeting driver regions, when applicable

• complete linear block of linear lesions if deployed

Secondary outcome

Performance: performance assessed by:

• percentage of RF focal ablation (touch up) to reach the primary performance endpoint

• procedural parameters (fluoro, ablation and total procedural times)

• complete freedom from documented AF or other atrial tachycardia (> 30 s), using 48-hour Holter monitor at 12 months post ablation, after a single procedure and off AAD (Anti Arrhythmic Drug) (includes a three month blanking period).

Study description

Background summary

Treatment of AF represents a significant health care burden. The estimated cost of the treatment of AF in 2005 was $6.65 billion per year, including the costs of hospitalization, in- and outpatient physician care, and medications. As many as 12 million people will have the condition by 2050.
Catheter ablation of AF is the treatment of choice for drug-resistant, symptomatic patients and is the most frequent ablation procedure performed worldwide. However, the main challenge remains in the field of AF ablation, probably being responsible for most ablation failures and the need for repeat procedures in a significant number of patients. It is recurrent pulmonary vein conduction.
Almost all patients experiencing recurrent AF after pulmonary vein isolation for AF have at least one reconducting and actively firing pulmonary vein responsible for arrhythmia recurrence. The importance of pulmonary vein reconnection has been confirmed in many studies and has led to the postulate that electrical reconnection of the veins is an important mechanism of AF recurrence following catheter ablation.
The rational for the CryoCure2 clinical study investigation is to evaluate a procedure and device that provides linear, transmural lesions for acute and long-term success of treating paroxysmal AF ablation without the need for repeat ablations.

Study objective

The objective of the study is to demonstrate the safety and performance of the Adagio Cryoablation System in patients with paroxysmale (PAF), persistent or Long-Standing Persistent Atrial Fibrillation.

Study design

80 patients with AF will be enrolled in prospective, multicenter, non-randomized and non-controlled investigation.

Intervention

The Cryoablation System achieves its intended purpose by creating and controlling the conditioning of Nitrogen to its critical point (CN2) within the Cryoablation console and subsequently creating an uninterrupted flow of this cooling agent (cryogen) through the Cryoablation catheter.
The Cryoablation Console contains an internal reservoir of liquid nitrogen that is used to pre-cool the CN2 cryogen to approximately -196°C. This cryogen is then delivered to the Cryoablation Catheter where it circulates within closed, internal lumens that are surrounded and insulated by a vacuum channel. The targeted cardiac tissue is exposed to cryogenic temperatures at the only non-insulated portion of the catheter. This non-insulated portion is located at

the distal tip and referred to as the freeze zone, which is continuously monitored and measured by an internal thermocouple.
The Cryoablation Catheter is delivered to the upper chambers of the human heart via common femoral vein cannulation and trans septal puncture, and positioned such that the freeze zone (treatment area) is adjacent to the targeted tissue. After the desired position and catheter-tissue contact have been obtained, a freeze cycle is initiated through the interactive touch screen on the console. The chilled CN2 fluid will begin circulating through the catheter and delivering treatment to the tissue adjacent to the freeze zone. The tissue that is in thermal contact with the distal freeze zone will cool to cryogenic temperatures, resulting in necrosis (ablation) of the tissue and the creation of a linear lesion. After the cryogen circulates back into the console, it is automatically heated up to ambient temperature and safely vented into the atmosphere.
The design of the Cryoablation Catheter enables the creation of continuous lesion defined by the shape of the catheter, providing a greater assurance that the arrythmogenic tissue/regions are isolated, which will result in normal sinus rhythm.

Study burden and risks

The ablation procedure is not experimentally. The Cryoablation system, which is used during the ablation procedure, is experimental. Pulmonary vein isolation ablation is a safe procedure, however as with any procedure, there are potential risks. The investigational device does not require deviation from the hospital regular medical care for this type of procedure. The use of the Cryoablation system is potentially just as safe as the usual treatment, however, since the treatment involves an experimental catheter, previously unknown side effects may occur, the effect of the treatment may be less than expected or there may be no effect at all.

Use of an ablation catheter could cause prolonged illness, permanent impairment of daily function, or in rare cases, death. These risks are typically controlled through the use of medications, and a variety of other devices and procedures.

The patient Atrial Fibrillation may improve while you are in this study; however, this cannot be promised. The results of this study may help people with Atrial Fibrillation in the future.

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. Patient is diagnosed with Paroxysmal (PAF), Persistent (PsAF) or Long-Standing Persistent atrial fibrillation for which an ablation procedure was deemed most appropriate therapy: Paroxysmal AF is defined as recurrent atrial fibrillation (AF) that terminates spontaneously within seven (7) days. Persistent AF is defined as: an episode lasting longer than seven (7) days, but less than one (1) year documented by consecutive ECG recordings of 100% AF greater than seven (7) days apart or an episode requiring electrical or pharmacological cardioversion after 48 hours of AF documented by continuous recording. Long-Standing Persistent AF is defined as continuous AF that lasts longer than one (1) year.
2. Reported incidence of at least one (1) documented episode of symptomatic AF during the twelve (12) months preceding trial entry (should be documented by rhythm strip or ECG).
3. Failure of at least one (1AAD for AF [class I or III, or AV nodal blocking agents such as beta blockers (BB) and calcium channel blockers (CCB)] as evidenced by recurrent symptomatic AF, or intolerable side effects due to AAD.

Exclusion criteria

1. Patient had any previous left atrial ablation.
2. History of any valvular cardiac surgical procedure, atrial septal defect closure device; or left atrial appendage closure device.
3. Coronary artery bypass grafting (CABG) procedure within the last 3 months.
4. Awaiting cardiac transplantation or other cardiac surgery within the next 12 months.
5. Atrial clot/thrombus on imaging such as on a trans-esophageal echocardiogram (TEE) performed within 48 hours of the procedure if deemed appropriate by the investigator.
6. History of a documented thromboembolic event within the past one (1) year.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2016
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	Adagio Cryoablation System
Registration:	No

Ethics review

Approved WMO

Date:	29-08-2016
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-10-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-03-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-02-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-08-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	09-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-10-2018
Application type:	Amendment
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
CCMO	NL56940.100.16