Randomized Evaluation of Atrial Fibrillation treatment with focal impulse and Rotor Modulation guided procedure (REAFFIRM)

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Primary Objective: Evaluate the safety and effectiveness of FIRM-guided procedures in addition to conventional ablation for the treatment of patients with persistent atrial fibrillation (AF).Secondary Objectives:•Evaluate the acute effectiveness of...

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

Summary

ID

NL-OMON43707

Source
ToetsingOnline

Brief title
REAFFIRM

Condition

- Cardiac arrhythmias

Synonym
Abnormal heartritme, persistent atrial fibrilation

Research involving
Human

Sponsors and support

Primary sponsor: Abbott Electrophysiology

Source(s) of monetary or material Support: Medisch hulpmiddelen bedrijf

Intervention

Keyword: Ablation, Atrial fibrillation, Rotormodulation

Outcome measures

Primary outcome

1. Safety endpoints: Freedom from serious adverse events related to the procedure within 7-10 days of the procedure; and Freedom from cumulative serious adverse events related to the procedure (including any repeat procedures required) within one year of the initial procedure .

2.2) Effectiveness endpoints: Single Procedure Freedom from AF/AT recurrence at 3 months; and Single Procedure Freedom from AF/AT recurrence from 3-12 months after the initial AF ablation procedure

Secondary outcome

1)The acute success of FIRM-guided procedure is defined as elimination of the source of arrhythmias identified by FIRMap

2) EQ-5D scores pre-procedure will be compared to those post-procedure at all time points separately and together.

Study description

Background summary

According to the American Heart Association, atrial fibrillation affects approximately 2 million Americans. Atrial fibrillation may reduce cardiac performance and may result in thrombus formation in the left atrium and thromboembolic events, such as stroke. Approximately 15% of all strokes occur

in people with atrial fibrillation. Ablation of atrial fibrillation that specifically targets approximately 2-3 mm outside of the pulmonary vein is currently a standard of care treatment in subjects with symptomatic atrial fibrillation who have failed drug therapy. Unfortunately, this procedure is time consuming, creates substantial damage in the left atrium due to the number of lesions required, and has mixed success with the best outcomes being 50-70% freedom from symptoms at 1 year post ablation. Also, as with any invasive procedure, patient complications may heighten with increased time and additional radiation exposure.

One of the major issues with the current procedure is the lack of knowledge about the critical regions of the heart that have the source rhythms causing and sustaining AF. Some very new technology developed based upon work done under NIH support at the University of California San Diego has shown promise in diagnosing these key source rhythms. Ablation to target these sources, called Focal Impulse and Rotor Modulation (FIRM) guided procedure, shows promise but need to be evaluated further.

Study objective

Primary Objective:
Evaluate the safety and effectiveness of FIRM-guided procedures in addition to conventional ablation for the treatment of patients with persistent atrial fibrillation (AF).
Secondary Objectives:
•Evaluate the acute effectiveness of FIRM-guided procedures in eliminating the source of arrhythmia.
•Quality of life outcomes.

Study design

This is a prospective, multicenter, randomized study to assess the safety and effectiveness of FIRM-guided procedures followed by conventional ablation including PVI versus a standard PVI procedure for the treatment of persistent atrial fibrillation.

Intervention

Block randomization using a web-based database system will be used to assign subjects (1:1) to the conventional AF ablation treatment without FIRM-guided diagnostic procedure, or to the FIRM-guided procedure followed by conventional AF ablation.

Study burden and risks

The potential risk do not differ from the risks associated with the

conventional/routine ablation procedure described in the Dutch Heart foundation;
- Hematoma Groin
- Thrombus cath, caused Stroke, TIA
- Allergic reaction on medication and material
- damage to a heart valve or the heart muscle

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.Male or female 18 - 80 years of age.
2.Experiencing at least two (2) documented episodes of persistent atrial fibrillation (including long standing persistent) during the 3 months preceding study entry with clinical indication for AF ablation per guidelines. At least one episode must be documented by rhythm strip or ECG.

3.Refractory, contraindicated, or intolerant to Class I or III anti-arrhythmic medications. Drug doses must be therapeutic and stable.
4.Oral anticoagulation required with either Novel Oral Anticoagulant (e.g. dabigatran, rivaroxaban, apixaban), Warfarin (therapeutic INR >= 2.0 for at least three weeks prior to randomization), or other similar standard-of-care oral anticoagulant therapy is required (aspirin is not considered similar) for those subjects who meet two or more of the following criteria:
a.Age 65 years or older
b.Diabetes
c.Coronary artery disease (CAD)
d.Prior stroke or transient ischemic attack
e.Congestive heart failure
f.Hypertension with systolic>165 mm Hg
5.Willingness and able to remain on anti-coagulation therapy for a minimum of 3 months post procedure for all subjects and at least 12 months post procedure if the patient has CHADS2 score >= 2.

Exclusion criteria

1.Presence of structural heart disease of clinical significance including:Coronary artery disease with either:
oCoronary artery bypass surgery (CABG) within the last six months, or
oStable/unstable angina or ongoing myocardial ischemia
b.Congenital heart disease where either the underlying abnormality or its correction prohibits or increases the risk of ablation.
2.NYHA Class IV.
3.Ejection fraction < 35%.
4.History of myocardial infarction (MI) within the past three months.
5.Any concomitant arrhythmia or therapy that could interfere with the interpretation of the results from this study.
6.ASD closure device, LAA closure device, prosthetic mitral or tricuspid valve and permanent pacemakers or defribrillator leads
7.Untreatable allergy to contrast media.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-01-2016
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	FirMap diagnostic cath.
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	10-11-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-02-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL53840.078.15