Randomized Evaluation of Redo Ablation Procedures of Atrial Fibrillation with Focal Impulse and Rotor Modulation Guided Procedures (Redo-FIRM)

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

Summary

ID

NL-OMON45547

Source
ToetsingOnline

Brief title
Redo-FIRM

Condition

- Cardiac arrhythmias

Synonym
Abnormal heart rhythm, persistent atrial fibrilation

Research involving
Human

Sponsors and support

Primary sponsor: Abbott Electrophysiology

Source(s) of monetary or material Support: Medische Hulpmiddelen Industrie

Intervention

Keyword: Ablation, Atrial fibrillation, Rotormodulation

Outcome measures

Primary outcome

The long-term effectiveness of FIRM-guided procedures versus conventional ablation shall be defined as:

• Freedom from atrial fibrillation AF/AT/AFL recurrence at 3 -12 months post procedure.

Freedom from AF/AT/AFL recurrence is defined as no documented episodes > 30 seconds with conventional non-invasive 7-day monitoring. In the case of a cardiac implanted electronic device (CIED), freedom from AF/AT/AFL recurrence is defined as no documented episodes > 30 seconds in a 1-week window at the follow-up visits, in addition to any symptomatic episodes with documented episode > 30 seconds. AT recurrence does not include episodes of CTI (cavotricuspidisthmus) dependent flutter.

Primary Safety Endpoints:

Acute success: Freedom from serious adverse events related to the procedure within 10 days of the procedure.

Long-term success: Freedom from procedure-related serious adverse events (including those related to repeat procedures) within one year of the initial procedure.

Secondary outcome

Acute Effectiveness

The acute success of FIRM-guided procedure is defined as elimination of the

source of arrhythmia identified by FIRMap as indicated by:

1. No evidence of the source on FIRMap immediately post-procedure, OR

2. Reduction of electrogram amplitude to <0.2mV in region

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

The primary objective is to evaluate the safety and effectiveness of FIRM-guided procedures in addition to conventional ablation for the treatment of persistent or paroxysmal atrial fibrillation (AF) in repeat ablation procedures.

The secondary objectives are: 1) to evaluate the acute success of FIRM-guided procedure in eliminating the source of arrhythmias, and 2) to evaluate quality

of life outcomes.

Study design

The study is designed as a prospective, multicenter, randomized, single-blind study to assess the safety and effectiveness of FIRM-guided procedures followed by a conventional repeat ablation procedure including PVI versus a standard PVI procedure for the redo-treatment of persistent and paroxysmal atrial fibrillation.

Intervention

Through randomization (1:1) subjects will be assigned to the conventional AF ablation treatment without FIRM-guided diagnostic procedure, or to the FIRM-guided procedure followed by conventional AF ablation.

Optional sub*study cohort enrollment: If the patient is disqualified on the day of the procedure because PV reconnection cannot be confirmed, the patient cannot be randomized / enrolled in the study. However, if AF can be sustained the patient may undergo FIRM*guided ablation and enroll in the sub*study cohort. The patient will be required to comply to all protocol follow*up requirements.The sub-study cohort data will be analyzed for safety and will not be counted towards the total study sample size (N=268).

Study burden and risks

The potential risk does 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. Has at least one (1) episode of spontaneous persistent or paroxysmal atrial fibrillation documented by rhythm strip/ ECG following the most recent ablation.
3. Had one (1) previous AF ablation after 01 January 2013, but NOT within the last 3 months. Detailed documentation of the previous ablation strategy is required.
4. Oral anticoagulation required with either Novel Oral Anticoagulant (NOAC) or Warfarin (in the case of Warfarin, therapeutic INR >= 2.0 for at least three weeks prior to randomization) 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. Congestive heart failure
e. 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 is on anti-coagulation pre-procedure or has CHADS2 score >= 2 (or CHADs-Vasc score >1).
6. Left atrial diameter < 6.0 cm via transthoracic echo or transesophageal echo; or <6.5 cm via CT or MRI up to 6 months pre-procedure with documented image of largest dimension, or intra-procedural ICE or atrial angiogram if CT/MRI not available.
7. Willingness, ability and commitment to participate in baseline and follow-up evaluations without participation in another clinical trial which may confound the results of this study, unless approved by the Sponsor.
8. Informed consent in writing from patient.

Exclusion criteria

1. Presence of structural heart disease of clinical significance including:
a. Coronary artery disease with either:
o Coronary artery bypass surgery (CABG) within the last six months, or
o Stable/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% (within previous 6 months).
4. Previous AF ablation within the last 3 months.
5. ASD closure device, LAA closure device, prosthetic mitral or tricuspid valve, or permanent pacemaker.
6. History of myocardial infarction (MI) within the past three (3) months.
7. Contra-indication to Heparin and Warfarin/other novel oral anticoagulants (e.g. dabigatran, rivaroxaban, apixaban).
8. Diagnosed atrial myxoma.
9. Any concomitant arrhythmia or therapy that could interfere with the interpretation of the results from this study.
10. Untreatable allergy to contrast media.
11. Severe electrolyte abnormalities at time of the ablation procedure or atrial fibrillation secondary to electrolyte imbalance, thyroid disease, or reversible non-cardiac cause.
12. Atrial fibrillation from a reversible cause (e.g., surgery, hyperthyroidism, pericarditis).
13. History of pulmonary embolus within one year of enrollment.
14. Acute pulmonary edema.
15. Atrial clot/thrombus on imaging such as on a trans-esophageal echocardiogram (TEE) performed within 72 hours of the procedure if deemed appropriate by investigator.
16. Any history of a cerebrovascular disease (including stroke or TIA) within the past 6 months.
17. Any anticipation of cardiac transplantation or other cardiac surgery within the next 12 months.
18. Significant pulmonary disease, (e.g. restrictive pulmonary disease, constrictive or chronic obstructive pulmonary disease) or any other disease or malfunction of the lungs or respiratory system that produces severe chronic symptoms and significantly increases risk to sedation or anesthesia.
19. Acute illness or active systemic infection or sepsis.
20. Any history of blood clotting abnormalities or bleeding abnormalities.
21. Life expectancy of less than 12 months.
22. Any Intramural thrombus, tumor, or other abnormality that precludes catheter introduction or safe manipulation.
23. Women known to be pregnant.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2017
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	FirMap diagnostic catheter
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-07-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-09-2017
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	NL60013.078.16