Utilizing Novel Dipole Density Capabilities to Objectively Visualize the Etiology of Recurrent Atrial Fibrillation Following a Failed AF Ablation (RECOVER AF)

Published: 09-11-2018
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The objective of the study is to evaluate the performance and efficiency of the AcQMap Imaging and Mapping System in an ablation retreatment procedure for recurrent atrial fibrillation following a failed AF ablation

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac arrhythmias
Study type	Observational non invasive

Summary

ID

NL-OMON46526

Source
ToetsingOnline

Brief title
RECOVER AF (CLP-AF-004) 3694/0003

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, cardiac arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Acutus Medical, Inc.
Source(s) of monetary or material Support: Acutus Medical;Inc.

Intervention

Keyword: AcQMap®, Failed AF ablation, Mapping, Recurrent atrial fibrillation

Outcome measures

Primary outcome

The measurable objectives are a descriptive analysis of the following:

- At the procedure conclusion, confirmation of electrical isolation of all

pulmonary veins and elimination/modification of all non-PV targets as

identified by the AcQMap* System

- Recording of all subjects who are atrial fibrillation free from events

lasting > 30 seconds at 6-, and 12-months as measured by a 48-hour continuous

ECG

o A subset analysis of AAD use

o A subset analysis of subjects with freedom from AF/AT/AFL events lasting > 30

seconds as measured by a 48-hour continuous ECG

- Documentation of procedure data including total time, fluoroscopy time,

ablation times for PVI, and ablation times for non-PV targets

- Safety * Recording of all device and procedure related safety events during

the procedure and throughout the duration of the study

Secondary outcome

not applicable

Study description

Background summary

Although much has been learned about the mechanisms of AF, they are not completely understood. Because of this, in the great majority of AF patients, it is not yet possible to precisely tailor an ablation strategy to a particular AF mechanism.

Three-dimensional (3D) electroanatomical contact and noncontact mapping systems have been reported to facilitate ablation of AF by identifying anatomical structures and highlighting the location of ablated sites. This can guide the initial ablation and help identify existing gaps in an incomplete lesion set. Additionally, electromagnetic navigation systems have been shown to substantially reduce the fluoroscopy time required for AF ablation.

The AcQMap*® High Resolution Imaging and Mapping System (AcQMap System) has been designed to provide information on cardiac dipole densities as a function of time and project that information on an image of a cardiac chamber. In this study, the AcQMap* System will collect data from the AcQMap* 3D Imaging and Mapping Catheter (AcQMap* Catheter) to create anatomical reconstructions of the chamber(s) being mapped and to create Dipole Density maps on those reconstructions. These maps will then be used to identify mechanisms of atrial fibrillation, which can be targeted for ablation.

Study objective

The objective of the study is to evaluate the performance and efficiency of the AcQMap Imaging and Mapping System in an ablation retreatment procedure for recurrent atrial fibrillation following a failed AF ablation

Study design

A prospective, single-arm, multi-center, multi-national, nonrandomized, post-market study designed to provide clinical data regarding the use of the AcQMap High Resolution Imaging and Mapping System during an atrial fibrillation retreatment ablation procedure. The patient population includes men and women, eighteen (18) years of age or older. The treatment plan must include evaluation and ablation (as indicated) of pulmonary vein reconnections plus AcQMap* guided non-PV substrate ablation. Subject assessments will occur at screening, procedure, hospital discharge, 3-, 6-, and 12-months.

Study burden and risks

The AcQMap* System provides automatic and instantaneous 3D displays of the

chamber surface and Dipole Density maps on that surface, which may be able to identify mechanisms of atrial arrhythmias that cannot be identified using standard tools. This has the potential of improving ablation efficiency and shortening procedure time. This may also prove to be more effective at verifying an appropriate endpoint to the ablation. This may provide the Investigator with an intuitive tool to rapidly identify and guide treatment of clinically-relevant targets for ablation. This may also positively impact long-term outcomes of maintaining sinus rhythm in the future.

There is; however, no guarantee that this will occur. Through the subject*s participation in this study, the information gathered will add to the understanding of Dipole Density Mapping. This knowledge may advance medical science and may benefit future subjects, as well as society at large.

Pre-clinical research and ongoing clinical studies have demonstrated that the system is safe for human use. All potential risks have been evaluated and mitigation strategies have been implemented to reduce potential risks to acceptable levels. Acutus Medical believes that the potential benefits of the system 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

IC 1 Male or female eighteen (18) years of age or older
IC 2 Currently scheduled for a repeat endocardial ablation of AF
IC 3 Willingness, ability, and commitment to participate in baseline and follow-up evaluations for the full length of the study
IC 4 Willingness and ability to give informed consent

Exclusion criteria

EC 1 In the opinion of the Investigator, any known contraindication to a left-atrial ablation or concerns for left-atrial thrombus
EC 2 No more than two (2) previous left-atrial ablations
EC 3 Atrial arrhythmias secondary to electrolyte imbalance, thyroid disease, or any other reversible or non-cardiac cause
EC 4 Structural heart disease or implanted devices as described below:
a. An implanted pacemaker or ICD
b. Previous cardiac surgery, ventriculotomy, or atriotomy (excluding atriotomy for CABG)
c. Previous cardiac valvular surgical or percutaneous procedure, or prosthetic valve
d. Interatrial baffle, closure device, patch, or PFO occluder
e. Presence of a left atrial appendage occlusion device
f. Unstable angina or ongoing myocardial ischemia
EC 5 History of blood clotting or bleeding disease
EC 6 Pregnant or lactating (current or anticipated during study follow up)
EC 7 Current enrollment in any study protocol sponsored by Acutus Medical or any other study that may impact the results of RECOVER AF
EC 8 Any other condition that, in the judgment of the investigator, makes the patient a poor candidate for this procedure, the study, or compliance with the protocol (includes vulnerable patient
population, mental illness, addictive disease, terminal illness with a life expectancy of less than two years, extensive travel away from the research center, etc.)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2019
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	AcQMap®
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	09-11-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	18-12-2018
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
ClinicalTrials.gov	NCT03368781
CCMO	NL65392.100.18