Utilizing Novel dipole density Capabilities to Objectively Visualize the Etiology of Rhythms in Atrial Fibrillation (UNCOVER-AF)

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

Summary

ID

NL-OMON42868

Source
ToetsingOnline

Brief title
UNCOVER-AF (CL-AF-002) 3694/0001

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

Intervention

Keyword: AcQMap, atrial fibrillation, electrophysiology, Mapping

Outcome measures

Primary outcome

The primary measurable objective is an analysis of the proportion of subjects who are free from device/procedure related Major Adverse Events (MAEs) that occur within the first 24 hours post-procedure. MAEs include any of the following:

- Death

- Cardiac perforation/tamponade

- Cerebral infarct, transient ischemic attack (TIA), or systemic embolism

- Major bleeding

- Mitral or tricuspid valvular damage

- Other serious adverse device effects (SADEs) adjudicated by an independent Clinical Events Committee (CEC) as *probably related* to the AcQMap System

Secondary outcome

Secondary measurable objectives include the following:

Safety Outcome Measure

- Recording and analysis of all identified adverse events (AEs) and adverse device effects (ADEs) through 12 months post-procedure. Events will be adjudicated by an independent Clinical Events Committee (CEC) for severity and relationship to the AcQMap.

Procedure Outcome Measure

- Analysis of the proportion of subjects with acute procedural (ablation)

success

defined as: Conversion to sinus rhythm (with or without DCCV) within 12 hours

of the procedure OR procedural conversion to atrial flutter, atrial tachycardia

or other organized supraventricular rhythm

- Procedure fluoroscopy time

- Ablation time to complete PVI

- Ablation time for non-PVI ablation

- Ablation time for right atrial ablation

- Number of DCCV completed during the procedure

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 clinical study is to evaluate the incidence of device- and procedure-related safety, efficacy, and efficiency (6-and 12-month outcomes) when using the AcQMap as an imaging and mapping system for ablation of persistent atrial fibrillation (AF).

Study design

The clinical study is a prospective, single-arm, multi-center, multi-national, non-randomized, post-market study designed to provide clinical data regarding the use of the AcQMap System during an ablation of persistent atrial fibrillation.

Study burden and risks

Pre-clinical research and current 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.

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 AF 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.

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

Scheduled for an ablation of persistent atrial fibrillation

Exclusion criteria

Any duration of continuous AF lasting longer than 12 months Previous AF ablation
Significant structural heart disease
Previous cerebral infarct
Major bleeding disorders
Pregnant or lactating

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2017
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	AcQMap
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-02-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT02825992
CCMO	NL59276.068.16