A randomized, controlled study to evaluate the reliability of the Ablacon Electrographic FLOW (EGF) algorithm technology (Ablamap® Software) to identify AF sources and guide ablation therapy in patients with persistent atrial fibrillation

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

Summary

ID

NL-OMON52465

Source
ToetsingOnline

Brief title
FLOW-AF

Condition

- Cardiac arrhythmias
- Cardiac therapeutic procedures

Synonym

Persistent Atrial Fibrillation

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Atrial-Fibrillation, Identify, Software, Sources

Outcome measures

Primary outcome

The primary endpoint events for this trial to assess the safety and effectiveness of the Ablamap® Software System to guide therapy for the treatment of persistent atrial fibrillation are as follows:

• Primary Safety Endpoint: Freedom from serious adverse events (SAEs) related to the procedure through 7 days following the randomization procedure.

• Primary Effectiveness Endpoint: Acute procedure success defined as the ability to successfully ablate AF sources identified by the EGF algorithm.

Secondary outcome

The following safety and efficacy secondary endpoints will be evaluated to support the results of the primary endpoints:

• Secondary Safety Endpoint: Freedom from serious adverse events (SAEs) related to the procedure through 12 months following the randomization procedure.

• Secondary Efficacy Endpoints:

o Consistency of sources identified by the Ablacon® EGF algorithm between the randomization procedure and any subsequent EGF-guided ablation procedures

o Freedom from documented episodes of AF recurrence following the blanking period (90 days post ablation) through 12 months

o Total number of EGF source ablations

o Total time of EGF source ablations

o Total fluoroscopy time and dose

o Overall procedure time

Study description

Background summary

Atrial fibrillation (AF) is the most common cardiac arrhythmia and is associated with increased mortality, morbidity and impaired quality of life. Catheter ablation has become the standard of care for symptomatic patients with drug-refractory AF and the cornerstone of ablation is the electrical isolation of the pulmonary veins (pulmonary vein isolation = PVI).1 Long-term effectiveness of an approach based on PVI as the sole ablation strategy is reported to be high for patients with paroxysmal AF (81.6% at 12 months, 73.8% at 24 months, and 68.1% at 36 months.2 However, the success rate of PVI is significantly lower with only up to 51% in patients with persistent AF.3 It is assumed that this is due to the fact that persistent AF is often driven by focal and reentrant activity in the atrial substrate rather than in the pulmonary veins.4 Accurate, enhanced mapping techniques that can localize those extra PV sources are essential to identify and guide ablation of these sources independently from PVI.
Narayan, et al., used a 64 pole-basket catheter to map AF using unipolar electrograms recorded in the right and the left atrium to construct spatiotemporal source maps.5 The technology was called Focal Impulse and Rotor Modulation (FIRM). Compared with patients undergoing conventional AF ablation, FIRM guided ablation initially seemed to be associated with a higher acute success and a better outcome as demonstrated in non-randomized studies. However, in randomized multi-center studies, significant benefit of FIRM guided ablation was not confirmed.6
Since Narayan*s pioneer work several other systems were developed to invasively map rotational activities: Biosense Webster Carto Finder uses phase mapping

applied to 64-pole basket catheter unipolar electrograms to identify rotors in the atrial wall.7 Acutus medical uses dipole density mapping with a 48-pole non-contact basket catheter to identify sources of excitation; CardioNXT uses small spiral catheters to search for AF-sources based on typical source pattern cross-correlation with coronary sinus catheter signals; Volta Medical detects dispersion of activation maps in bipolar electrogram signals recorded using the PentaRay catheter with five splines and 20 poles.8,9,10 However, none of these newer mapping systems have demonstrated the clinical relevance of these extra-pulmonary vein sources of excitation in the atrial myocardium over a period longer than a few seconds. As such, the ability to identify and ablate relevant non-pulmonary vein foci/triggers to improve freedom from AF post-ablation has not been achieved to date.
The recently developed Electrographic Flow (EGF) Mapping system (Ablamap® Software, Ablacon, Wheat Ridge, CO) is a technology based on a novel algorithm being able to (1) discriminate between active sources of excitation and passive rotations which do not generate action potentials and (2) estimate the average activity of such a source during a time interval such as one minute.11 It has been shown that only those sources that are generating excitation and that are active more than a quarter of the time are significant predictors for AF recurrence after PVI.12 The EGF system uses a velocity vector matrix created through an optical flow analysis applied on surface voltage movies created using a minimal energy algorithm from endocardial unipolar electrograms. The analysis is conducted with the 64-electrode mapping basket catheter, which was also used for FIRM-guided rotor mapping.
The goal of this clinical trial is to evaluate this novel mapping software for identifying AF sources in humans with persistent AF to optimize ablation success in this challenging and heterogeneous patient population. To date no EGF-guided ablation of AF sources has been performed in a controlled trial.

Study objective

The objective of this study is to evaluate the reliability of the Ablacon Electrographic Flow (EGF) algorithm technology (Ablamap® Software) to identify AF sources and guide ablation therapy in patients with persistent atrial fibrillation.

Study design

Study Design:

The FLOW-AF study is a prospective, multi-center study conducted to assess the safety and efficacy of the Ablamap® Software System for patients with a history of persistent atrial fibrillation. This study will enroll up to 100 subjects.
Subjects Patients that present with persistent atrial fibrillation and, meet eligibility, and have had a previous ablation procedure prior to being enrolled in the study will be eligible for enrollment. All subjects must be in AF at

the time of the procedure.

Recurrence Procedures: Subjects who present with symptoms of AF at any time following the Randomization procedure and are indicated for a re-repeat ablation (regardless of randomization assignment).

Study burden and risks

1. Anticipated Risks associated with the Ablamap® Software
There are no patient or user safety issues or hazards identified for the Ablamap® Software in the clinical data analyzed within a comprehensive literature review. Internal data generated as part of the risk analysis of the Ablamap® Software indicates there were no patient or user safety issues or hazards identified.
The Ablamap® Software Safety Classification per BS EN 62304:2006+A1:2015 is Safety Class A where the hazard probability is Improbable and the hazard severity is Negligible.
Current market experience shows no evidence to suggest that the Ablamap® Software poses any safety issues or any hazards and there are no safety issues or hazards that outweigh the benefits of the system.
2. Risks Associated with Participation in the Clinical Study
There are no specific tests outside the standard practice required by this clinical study protocol. Therefore, there is no foreseen increased risk to subjects for participating in the clinical study.
3. Anticipated Benefits
The benefit to the subjects enrolled in this study is the potential for improved judgement by the clinician due to the additional information provided by the Ablamap® software. Specifically, the software analyses will guide and support treatment therapy to allow targeted ablation techniques for the clinician which may improve acute and long-term clinical outcomes.

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. Suitable candidate for intra-cardiac mapping and ablation of arrhythmias
2. Above eighteen (18) years of age or of legal age to give informed consent specific to state and national law
3. Subjects with a history of documented symptomatic, persistent or longstanding persistent atrial fibrillation < 36 months
4. Subject agrees to comply with study procedures and be available (geographically stable) for follow-up visits for at least 12 months
5. Treatment of atrial fibrillation with ablation therapy presenting with recurrent symptoms of AF

Exclusion criteria

1. LA diameter > 5.5 cm.
2. Left ventricular ejection fraction (LVEF) < 35%
3. Presence of intramural thrombus, tumor or abnormality that precludes vascular access, catheter introduction or manipulation
4. Coagulopathy, bleeding diathesis or suspected procoagulant state
5. Known allergies or intolerance to anticoagulant and antiplatelet therapies to be used in conjunction with the study or contrast sensitivity that cannot be adequately pre-treated prior to the ablation procedure
6. Positive pregnancy test results for female patients of childbearing potential or breast feeding
7. Acute or chronic medical condition that in the judgment of the investigator would increase risk to the patient or deem the patient inappropriate to

participate in the study
8. Mitral valve stenosis and/ or severe mitral regurgitation
9. Valvular atrial fibrillation
10. Prosthetic valves
11. NYHA Class IV
12. History of MI within 3 months prior to procedure
13. Atrial septal defect (ASD) or Left Atrial Appendage (LAA) closure device.
14. Atrial fibrillation from a reversible cause (e.g., surgery, hyperthyroidism, sarcoidosis or pericarditis)
15. Life expectancy < 12 months based on medical history or the medical judgement of the investigator
16. Presence of any transvenous pacing, ICD, or CRT leads

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2020
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	17-12-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	25-05-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	30-07-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	20-11-2020
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-12-2020
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	NL71156.078.19