A prospective, single arm, multi-center, clinical evaluation of the Ablacath* Mapping Catheter and Ablamap® System utilizing Electrographic Flow (EGF) mapping to resolve extra-pulmonary vein sources Atrial Fibrillation sources and guide ablation therapy.

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Demonstrate clinical safety and effectiveness of the Ablacath* Mapping Catheter and Ablamap® System in patients with paroxysmal (Redo only) or persistent or long-standing persistent AF. Phenotype patients and demonstrate the prognostication power of...

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

Summary

ID

NL-OMON56533

Source
ToetsingOnline

Brief title
RESOLVE-AF TRIAL

Condition

- Cardiac arrhythmias

Synonym
atrial fibrillation, irregular heartrhythm

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Ablation, Atrial Fibrillation, Electrographic Flow, Mapping

Outcome measures

Primary outcome

Primary Safety Endpoint

The primary safety endpoint is defined as freedom from a composite of serious adverse events (SAEs) occurring within 7 days from the index procedure as adjudicated by an independent CEC for relatedness to procedure or device.

The primary safety device- or procedure-related SAE composite will be the combined rate of the following events:

• Atrioesophageal fistula

• Major bleeding complication (BARC 2 or higher)

• Catheter entrapment/entanglement

• Cardiac perforation/tamponade

• Death

• Extended hospitalization (>7 days) related to device or procedure

• Myocardial infarction

• Phrenic nerve paralysis (> 3 months post-procedure)

• Acute pulmonary edema

• Acute or symptomatic pulmonary vein stenosis (>70%)

• Stroke/CVA

• Systemic thromboembolism

• Transient ischemic attack (TIA)

• Vagal nerve injury requiring chronic treatment

• Valvular damage

• Vascular access complication requiring intervention

Primary Effectiveness Endpoint

• Freedom from documented AF episodes lasting > 30 seconds (with or without AAD) following the index ablation through 12-months.

• Demonstrate predictive value of EGF phenotype for ablation outcome.

Secondary outcome

Secondary Endpoints

Secondary endpoints to characterize the performance of the Ablacath* Mapping Catheter and Ablamap® System will include:

• Freedom from a composite of SAE occurring within 30 days from post-index ablation procedure as adjudicated by an independent CEC for relatedness to the procedure or device.

• Single Procedure: Freedom from documented AF/AFL/AT episodes lasting >30 seconds (with or without AADs) through 12-months following the index ablation procedure.

• One or More Procedures: Freedom from documented AF/AFL/AT episodes lasting >30 seconds (with or without AADs) through 12-months after the final ablation procedure.

• Overall reduction in burden of AF for subset of patients with implanted loop recorders

• Comparison of 12-month freedom from AF between those with active sources above threshold and those without active sources above threshold.

• Identification of number and location of identified sources

• Overall procedure time

• Total fluoroscopy time

• Total EGF-guided mapping time

• Total EGG-guided procedure time

Study description

Background summary

A prospective, single arm, multi-center, clinical evaluation of the Ablacath* Mapping Catheter and Ablamap® System utilizing Electrographic Flow (EGF) mapping to resolve extra-pulmonary vein sources of Atrial Fibrillation and guide ablation therapy.

Study objective

Demonstrate clinical safety and effectiveness of the Ablacath* Mapping Catheter and Ablamap® System in patients with paroxysmal (Redo only) or persistent or long-standing persistent AF.
Phenotype patients and demonstrate the prognostication power of Electrographic Flow (EGF®) maps among all subjects using 12-month follow-up outcomes following EGF-guided mapping and ablation.

Study design

The RESOLVE-AF Trial is a prospective, single-arm, multi-center, clinical investigation of the Ablacath* Mapping Catheter and Ablamap® System utilizing the Ablamap® Electrographic Flow (EGF) algorithm to identify AF sources to guide ablation therapy. This study will enroll up to 500 subjects across up to 25 centers in Europe, United States and Canada.

Intervention

Not applicable

Study burden and risks

The possible risks to which you are exposed in this investigation, due to the Ablacath* Mapping Catheter/System are similar to those risks from a standard of care catheter mapping and ablation.

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 atrial fibrillation
2 Atrial fibrillation documented by electrocardiographic data (e.g., ECG, Holter, rhythm strips, loop recorder) within 6 months prior to the index ablation procedure
3 Above eighteen (18) years of age or of legal age to give informed consent specific to state and national law
4 Left atrial (LA) diameter <= 6.5 cm or LA volume index <= 50 mL/m2 (use whichever measure is available or if both available, use the lesser of the two to qualify)

Exclusion criteria

1. De Novo paroxysmal AF
2. AF from a reversible cause (e.g., surgery, hyperthyroidism, sarcoidosis, or pericarditis, etc.)
3. Cardiac surgery or intervention within the past 90 days (e.g. percutaneous coronary intervention, ablation for ventricular arrhythmias, left atrial appendage occlusion devices, atrial septal defect closure devices, transcatheter aortic valve replacement)
4. Presence of transvenous pacing or defibrillator leads or an atrial leadless pacemaker
5. Myocardial infarction within the past 90 days
6. Severe valvular disease or prosthetic valve(s)
7. Contraindication to therapeutic anticoagulation
8. Decompensated heart failure or New York Heart Association (NYHA) Functional Class IV
9. Positive pregnancy test
10. Any other contraindication to an intracardiac mapping and ablation of atrial arrhythmias
11. Enrollment in another investigational study evaluating another device, biologic or drug

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2024
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Ablacath Mapping Catheter and Ablamap System
Registration:	No

Ethics review

Approved WMO Date:	06-02-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-05-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	16-07-2024
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	NCT05883631
CCMO	NL84776.100.23