High-Density Wave Mapping in Subjects with Atrial Fibrillation as a Predictor of Recurrence After a Single Ablation Procedure Using a PVI-Only Strategy

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

Summary

ID

NL-OMON48012

Source
ToetsingOnline

Brief title
Wave-Map AF

Condition

- Cardiac arrhythmias

Synonym
arrythmia, artrial fribrillation

Research involving
Human

Sponsors and support

Primary sponsor: Abbott

Source(s) of monetary or material Support: Abbott

Intervention

Keyword: Ablation, Atrial Fibrillation, High-Density, Wave-mapping

Outcome measures

Primary outcome

The primary outcome is one-year success, defined as freedom from AF/AFL/AT after removal from antiarrhythmic drug therapy as assessed from the end of the 3-month blanking period to 12 months following a single ablation procedure.

Secondary outcome

See page 13 and 14 of the protocol (versie A, 20 februari 2019).

Acute procedural success, defined as electrical isolation of all pulmonary veins.

Success post blanking period through 12 months using different definitions, including:

-Freedom from symptomatic AF/AFL/AT after removal from AAD therapy

-Single procedure clinical success defined as freedom from symptomatic AF/AFL/AT without a new or increased dose of class I or III AAD

-Freedom from AF/AFL/AT

Data from EnSite maps using both HD Wave and Standard mapping modes in both sinus rhythm and AF including but not limited to:

-Left atrial area using different boundaries (e.g. with and without LAA, etc.)

-Low voltage area and proportion of left atria with low voltage using

different thresholds for low voltage

Rates of recurrence not due to PVI gap for subjects with repeat

electrophysiology studies

LA volume and diameter

Adverse events including any device-, procedure-, or death-related events

Other baseline characteristics including but not limited to:

-Time with AF

-Type of AF

-Sex / BMI

-General medical history / Cardiovascular history / Arrhythmia history

-NYHA classification / LVEF

-Presence of pacemaker

Procedural characteristics, including but not limited to:

-Power, temperature, and contact force

-Procedure time / Mapping time / Fluoroscopy time

-Cardioversions (if applicable)

-Anesthesia

Study description

Background summary

This study will provide insight into how substrate characteristics, as measured by GRID, can identify subjects who will not benefit from additional substrate modification beyond PVI. This may result in future recommendations for treatment based on HD Wave mapping of baseline substrate so that additional,

unnecessary ablations along with their potential risks can be avoided. There have been no studies to date correlating substrate characteristics, as measured using HD Wave mapping, to outcomes. Results of this study may also help design future studies on GRID to further investigator treatment algorithms for atrial substrate modification in AF.

Study objective

The primary objective of this study is to characterize low-voltage substrate, as identified via HD Wave mapping in sinus rhythm and identify associations with 12-month recurrence rates after a single pulmonary vein isolation with a contact force RF ablation catheter.
Other objectives of this study include:
* Analyze additional maps and data collected with GRID and associations with 12-month recurrence rates, such as:
o Voltage maps using different configurations recreated post procedure
o Voltage maps using different thresholds for low-voltage
o Fractionation maps
* Collect mapping data in AF to support future research and development.
* Support future study designs to identify optimal treatment approaches for individual patients.

Study design

This is a single-arm, multicenter, post-market study. There will be no randomization. The purpose of the study is to determine correlations between low-voltage substrate, as identified via HD Wave mapping, and recurrence of atrial fibrillation after a single pulmonary vein isolation with a contact force RF ablation catheter.

Study burden and risks

The risk of participation is minimal. The burden may be higher for procedures where sedation or anesthesia is being administered. The accompanied risks may be higher due to potentially longer mapping times.
Because fluoroscopy is being used to control the cardiac mapping procedures and ablation procedure, a potentially longer mapping procedure can expose the subject to more X-rays. The total risk of this dose is considered small.

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. Documented atrial fibrillation with planned endocardial ablation procedure
2. Age 18 years or older
3. Able and willing to provide written informed consent prior to any clinical investigation related procedure
4. Able and willing to complete all required study procedures through 12 months

Exclusion criteria

1. Long-standing persistent atrial fibrillation defined as continuous AF greater than 12 months in duration
2. Previous ablation or surgery in the left atria
3. Implanted left atrial appendage occluder
4. Implanted mitral or tricuspid valve replacement
5. Implanted cardiac defibrillator (ICD)
6. Participation in another clinical investigation that may confound the results of this study
7. Pregnant or nursing

8. Presence of other anatomic or comorbid conditions, or other medical, social, or psychological conditions that, in the investigator*s opinion, could limit the subject*s ability to participate in the clinical investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results.
9. Life expectancy less than 12 months

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-08-2019
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Advisor HD Grid Mapping Catheter;Sensor Enabled;EnSite Precision Cardiac Mapping System v 2.2 or l
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-01-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NCT03882021
CCMO	NL70507.042.19