Advisor HD Grid Observational Study

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The aim of this study is to quantify and characterize the outcomes of radiofrequency (RF) ablation after, and the utility of electroanatomical mapping with the Advisor* HD Grid Mapping Catheter, Sensor Enabled* (hereafter called *HD Grid*) and...

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

Summary

ID

NL-OMON48299

Source
ToetsingOnline

Brief title
Advisor HD Grid Observational Study

Condition

- Cardiac arrhythmias

Synonym
arrhythmia, atrial fibrillation (PersAF) or ventricular tachycardia (VT)

Research involving
Human

Sponsors and support

Primary sponsor: Abbott
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: AF ablation, mapping catheter, VT ablation

Outcome measures

Primary outcome

To quantify and characterize the acute- and long-term success rate of RF ablation after electroanatomical mapping with HD Grid, the following will be summarized:

* Rate of acute success defined as the proportion of subjects who receive HD Grid mapping and RF energy delivery resulting in acute termination of clinical arrhythmia.

* Rate of long-term success defined as the proportion of subjects who receive HD Grid mapping and RF energy delivery with the following pre-defined procedural endpoints:

Persistent AF :

o freedom from all atrial arrhythmias (AF/AFL/AT) greater than 30 seconds (as documented by 48-hr Holter at 12-month follow-up) and new or increased dose of class I/III antiarrhythmic drug (AAD).

o freedom from all atrial arrhythmias (AF/AFL/AT) greater than 30 seconds (as documented by 48-hr Holter at 12-month follow-up) on or off class I/III AAD.

VT :

o freedom from recurrence of sustained monomorphic VT and new or increased dose of class I/III AAD at 6-month follow-up

o freedom from recurrence of sustained monomorphic VT on or off class I/III AAD

at 6-month follow-up.

Secondary outcome

The second objective is to quantify and characterize the use of HD Grid and EnSite Precision with HD Wave in the electroanatomical mapping of PersAF or VT in real-world clinical settings. This will be done through a summary of the following:

Use of HD Grid and EnSite Precision with HD Wave will be quantified and characterized through the summary of the following:

* Overall procedure time: defined as time from initial catheter insertion to final catheter removal.
* Radiofrequency (RF) time: defined as duration of time RF energy is delivered
* Fluoroscopy time: defined as total time subject is exposed to fluoroscopy
* Mapping time associated with mapping arrhythmia:
* Number of mapping points collected:
* Number of mapping points used:
* Number of used mapping points per minute:
* Substrate characteristics identified:
* Ablation strategy(s) used:
* Role of HD Wave map relative to along-the-spline map in ablation strategy decision: as assessed by physician survey comparing maps generated with HD Wave electrode configuration to along-the-spline electrode configurations.
* Maneuverability of HD Grid catheter:
* HD Grid electrogram quality relative to ablation catheter electrograms: as

assessed by physician survey

Study description

Background summary

Atrial Fibrillation (AF) is a supraventricular arrhythmia characterized by rapid and irregular activation in the atria, and, when maintained greater than seven days, is known as Persistent AF (PersAF). Patients with PersAF have an increased risk of stroke and are likely to develop life-threatening problems such as tachycardia-induced cardiomyopathy and congestive heart failure which can increase mortality. Restoration and maintenance of sinus rhythm in these patients may confer mortality benefit.
Sustained monomorphic VT is a cardiac arrhythmia emanating from the ventricles at a rate greater than 100 bpm that is sustained longer than 30s or requires intervention due to hemodynamic instability. Sustained VT is associated with increased mortality risk including risk of sudden cardiac death.
Catheter ablation is an established treatment option for PersAF and VT. Ablation strategies target the pathogenic mechanisms that initiate and perpetuate abnormal electrical activity within the heart including abnormal substrate. However, identifying and eliminating the pathogenic mechanisms is not straightforward.
Recent advancements in high-density three-dimensional catheter mapping strategies enable the evaluation of such electrophysiologic characteristics that are used for identifying the mechanisms responsible for PersAF and VT. Identification of electrophysiological characteristics depends on the ability of mapping catheter electrodes and electrode pair electrograms to detect voltage characteristics.
Accurate electrogram depiction of underlying substrate is limited by adequate bipole orientation which can be challenging to achieve with traditional linear mapping catheters. The Advisor* HD Grid, Sensor Enabled* (HD Grid) diagnostic mapping catheter with equispaced multipolar grid electrodes provides known bipole spacing in orthogonal directions, thereby providing the ability to discriminate voltage differences in two directions for enhanced directionality and amplitude detection. This is done by using the HD Wave electrode configuration with AutoMap best duplicate enabled during electroanatomical map creation. It is hypothesized that the use of HD Wave mapping will allow high-resolution substrate identification, but the impact of this mapping catheter and configuration on the subsequent ablation strategy used by physicians remains unknown and is therefor investigated.

Study objective

The aim of this study is to quantify and characterize the outcomes of

radiofrequency (RF) ablation after, and the utility of electroanatomical mapping with the Advisor* HD Grid Mapping Catheter, Sensor Enabled* (hereafter called *HD Grid*) and EnSite Precision* Cardiac Mapping System (SV 2.2 or higher, hereafter called *EnSite Precision*) with HD Wave Vmax voltage mapping (hereafter called *HD Wave*) in subjects with PersAF or VT in real-world clinical settings. This will be completed through the assessment of two main objectives which are as follows:

Outcomes Objective:
The first objective is to quantify and characterize the acute- and long-term success rate of RF ablation after electroanatomical mapping with HD Grid and EnSite Precision with HD Wave in subjects with PersAF or VT.

Utility Objective:
The second objective is to quantify and characterize the use of HD Grid and EnSite Precision with HD Wave in the electroanatomical mapping of PersAF or VT in real-world clinical settings.

Study design

This is a prospective, non-randomized, multicenter observational study.

Study burden and risks

The risk of the participation to the study is minimal. The burden is limited to answering the 2 questionnaires at different visits (baseline, 6 months follow up and 12 months follow up. The use of the HD Grid mapping catheter is an additional procedure for patients participating in this study. The HD Grid mapping is no standard of care treatment. The holterrecording with AF patients will be longer (48h) than in the normal standard of care(24h).

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. Subject must provide written informed consent for study participation and willing and able to comply with the protocol described evaluations and follow up schedule.
2. Over 18 years of age
3. Indicated for cardiac electroanatomical mapping and RF ablation procedure to treat PersAF or VT
4. Subject is diagnosed with either PersAF OR VT as defined by:
a. Persistent AF <= Documented symptomatic persistent AF defined as continuous atrial fibrillation that is sustained beyond 7 days but less than 12 months
b. VT <= Sustained monomorphic ventricular tachycardia with record of VT event within last 6 months and history of prior myocardial infarction

Exclusion criteria

1. Life expectancy less than 12 months
2. Women who are pregnant or nursing
3. Known intracardiac thrombus or myxoma verified within 48 hours of index ablation procedure
4. Myocardial infarction (MI) or unstable angina, or previous cardiac surgery within 60 days of index ablation procedure
5. Percutaneous coronary intervention (PCI) within 30 days of index ablation procedure
6. Documented cerebroembolic event within the past 12 months (365 days)
7. History of valve repair, presence of a prosthetic valve, or severe mitral regurgitation thought to require valve replacement or repair within 12 months
8. Awaiting cardiac transplantation or other cardiac surgery within the next 12 months (365 days)

9. Current acute illness or active systemic infection or sepsis
10. Currently enrolled in another clinical study that could confound the results of this study
11. Any cause for contraindication to ablation procedure or systemic anticoagulation
12. 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 study or to comply with follow-up requirements, or impact the scientific soundness of the clinical study results.
13. Vulnerable patient or individuals whose willingness to volunteer in a study, in the judgement of investigator or public authorities, could be unduly influenced by lack of or loss of autonomy
14. Indication-specific exclusion criteria including:
a. PersAF:
i. PersAF felt to be secondary to electrolyte imbalance, uncontrolled thyroid disease, or reversible or non-cardiac cause.
ii. Prior catheter ablation for AF beyond pulmonary vein isolation
iii. LAD > 55 mm (parasternal long axis view)
iv. LVEF < 40%
v. Uncontrolled heart failure or NYHA function class III or IV
vi. Presence of implanted ICD/CRT-D
b. VT:
i. VT/VF thought to be from channelopathies
ii. Active ischemia or other reversible cause of VT
iii. Incessant VT at time of procedure
iv. Implanted with a ventricular assist device (VAD) (e.g. TandemHeart)
v. Chronic NYHA Class IV heart failure
vi.Ejection fraction < 15%

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-09-2019
Enrollment:	100

Type:	Actual

Medical products/devices used

Generic name:	Advisor HD Grid Mapping Catheter;Sensor Enabled and EnSite precision with HD wave
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-05-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL68033.098.18