Vision-MR Ablation Catheter 2.0 for Treatment of Type I Atrial Flutter

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The purpose of the VISABL-AFL study is to demonstrate safety and efficacy of RF ablation of type I atrial flutter (AFL) with the Vision-MR Ablation Catheter 2.0 in conjunction with the Osypka HAT 500 RF generator and irrigation pump. Data collected…

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

Summary

ID

NL-OMON57367

Source
ToetsingOnline

Brief title
VISABL-AFL study

Condition

- Cardiac arrhythmias

Synonym
Atrial Flutter, Cardiac arrhythmia

Research involving
Human

Sponsors and support

Primary sponsor: Imricor Medical Systems, Inc
Source(s) of monetary or material Support: Imricor Medical Systems Inc. de sponsor van de studie financierd het onderzoek

Intervention

Keyword: Ablation, Atrial Flutter, Cardiac arrhythmia

Outcome measures

Primary outcome

Primary Efficacy Endpoint:

Confirmation of bidirectional conduction block of the CTI following the last RF application with the Vision-MR Ablation Catheter 2.0 and Osypka HAT 500 RF generator & irrigation pump.

Acceptance Criteria: Performance goal of a lower, one-sided 95% confidence bound of 80% success rate for acute bi-directional block

Primary Safety Endpoint:

A composite of the following serious adverse events through 7 days post-procedure as adjudicated by an independent clinical events committee:

• Cardiac perforation/tamponade

• Cerebrovascular accident (CVA)

• Transient ischemic attack (TIA)

• Complete heart block

• Myocardial infarction

• Pulmonary embolism

• MR-related serious adverse events

• Unanticipated device related serious adverse events

• Death

Acceptance Criteria: Performance goal of an upper, one-sided 95% confidence

bound of 7% for the rate of subjects experiencing at least one of the composite serious adverse events adjudicated by an independent clinical events committee

Secondary outcome

Secondary Endpoints:

Chronic Efficacy: The percent of subjects without documented type I atrial flutter recurrence at 3 months (90 days) post procedure.

Safety: Serious adverse events rate during the clinical investigation as adjudicated by an independent clinical events committee

Ancillary Endpoints:

• Procedure characterization:

• Total procedure time

• Procedure room occupation

• RF time per patient

• Number of RF applications per patient

• Total saline solution perfused

• Use of fluoroscopy (and fluoroscopy time, characterize DAP (Dose Area Product) as available) - if required to complete type I atrial flutter ablations

• Use of an investigational mapping and navigation software (not used to make diagnostic or therapy decisions during the procedure) - European sites only

• Performance metrics for accessory investigational devices

• Physician experience survey characterization

• Performance of supportive investigational devices (e.g., Vision-MR Diagnostic Catheter, Advantage-MR EP Recorder/Stimulator System, NorthStar Mapping System,

Vision-MR Dispersive Electrode, accessory cables)

• Chronic efficacy considering only subjects off AADs after the procedure a

success

Study description

Background summary

Typical or type I atrial flutter (AFL) is a macroreentrant atrial tachycardia that propagates at the tricuspid annulus in the right atrium, runs up the atrial septum, counter-clockwise or clockwise around the atrium and through the cavotricuspid isthmus (CTI). It usually presents as mainly negative atrial deflections in the inferior leads with a 'saw-tooth pattern' at rates of 240-350 bpm per minute.
The incidence of atrial flutter in the US is 88/100,000 and increases exponentially with age (Granada, 2000). Ablation of recurrent symptomatic type I AFL is a class I indication and a relatively straightforward procedure with a low complication and high success rate (Brugada; 2020, Natale, 2000). The procedures are anatomically guided with therapy delivery targeted along the cavotricuspid isthmus (CTI) in the right atrium.

Currently in the US, ablation procedures are performed within the cardiac catheterization (cath) lab under x-ray and fluoroscopy to guide catheter navigation within the anatomy. While mapping and navigation software is available to create renderings of the cardiac anatomy, and intracardiac echo (ICE) may provide 2D views, 3D visualization of anatomic features is limited in this environment. In addition, the use of x-ray exposes the patient and the clinician to potential risks of ionizing radiation.

Performing the procedure in the magnetic resonance imaging (MRI) environment can provide the patient and clinician safety benefits by limiting exposure to ionizing radiation, and potential procedural benefits by leveraging real-time MRI of anatomical features (Barkhausen, 2017). Specifically, anatomical features such as deep *pouches* on concave morphology of the CTI may require accurate manipulation and navigation of the catheter to complete the ablation procedure. These abnormalities (found in 11% of AFL patients (Baccillieri, 2019)) are not visible with x-ray and are associated with increased procedure times and complications in the traditional cath lab (Baccilleri, 2019; Heidbüchel, 2000; Da Costa, 2004; Regoli, 2018). Although ICE is exceedingly helpful for such cases, it adds additional costs, requires prior expertise, and is not used in the majority of AFL cases. Real-time MRI provides clinicians visualization of these anatomical structures to guide therapy delivery and may

reduce procedure time.

Devices to perform real-time MR-guided cardiac electrophysiology studies and ablation procedures have been in development over the past 10+ years (Nazarian, 2008; Hoffmann, 2010; Sommer, 2013; Grothoff, 2014; Hilbert, 2016; Chubb, 2017; Paetsch, 2019). Recently Imricor Medical Systems (Imricor, Burnsville, MN) launched the first CE marked MR-guided ablation catheter (Vision-MR Ablation Catheter) and Electrophysiology (EP) system in Europe for treatment of type I atrial flutter.

The Vision-MR Ablation Catheter is designed to function and handle similar to traditional marketed radiofrequency (RF) ablation catheters used in the cath lab under x-ray and fluoroscopy. This design, along with starting with a straight-forward, anatomically guided ablation procedure (type I atrial flutter ablations), allows physicians to optimize the MR-specific workflows and imagining techniques for potentially more complex MR-guided procedures in the future.

Study objective

The purpose of the VISABL-AFL study is to demonstrate safety and efficacy of RF ablation of type I atrial flutter (AFL) with the Vision-MR Ablation Catheter 2.0 in conjunction with the Osypka HAT 500 RF generator and irrigation pump.

Data collected from this trial will be used to support US pre-market application of the Vision-MR Ablation Catheter 2.0 and Osypka HAT 500 generator/irrigation pump with the proposed indication for use in treatment of type I atrial flutter in patients 18 years or older.

Data on the performance and safety of supportive investigational products (including the Vision-MR Diagnostic Catheter, Vision-MR Dispersive Electrode, Advantage-MR EP recorder and stimulator, the NorthStar Mapping System) will also be collected prospectively during this investigation.

The follow-up period is 3 months.

Generally the tests performed within the study are standard of care, limiting the risk of participating in the study for the patients. At some sites it can be that the follow-up visits are not standard of care. In that case the extra visits and data collection compared to standard of care will allow for closer monitoring of the patient, which is important for identifying and management potential adverse events as well as facilitation of the collection of more comprehensive data of the investigational device(s).

Study design

Imricor is sponsoring the VISABL-AFL clinical investigation. The study is a prospective, single-arm, multi-center, global investigational study of the safety and efficacy of type I atrial flutter ablation procedures performed with the Vision-MR Ablation Catheter 2.0 and Osypka HAT 500 RF generator and irrigation pump.

Site selection will include sites in the US and Europe, with an enrollment cap of 50% of the total enrollment population coming from outside the US.

The VISABL-AFL clinical investigation is expected to run for approximately 12 months (9months for subject enrollment and 3-month follow-up of the final subject).

Intervention

Phase 1: Set-Up and Vascular Access
Following sedation, place the appropriate ECG electrodes and MRI body coil on the chest and place the Vision-MR Dispersive Electrode on the leg. The subject will be connected to the Invivo Expression patient monitoring system that will allow wireless monitoring. Vascular access will be obtained for both the diagnostic and ablation catheters in the femoral vein(s).

Phase 2: Ablation under MR Guidance
Position subject in MRI, perform standard safety checks. Perform pre-procedure scans to obtain cardiac shells for mapping and guidance software (NorthStar). Visualize catheter access in real-time MRI, the physician will then Insert and advance the Imricor Vision-MR Diagnostic Catheter into the lower inferior vena cava from the femoral vein access point. Image the catheter tip using active catheter imaging (or optionally, the NorthStar Mapping System) to advance the catheter into the coronary sinus (CS). Following the above the physician will advance the Imricor Vision-MR Ablation Catheter 2.0 to the right atrium in the same manner as in the previous step with the diagnostic catheter. The subject's fluid balance will be monitored during the procedure to avoid fluid volume overload per standard of care.
After navigating the ablation catheter to the desired ablation target location(s) identified via the imaging software. Ablation will be performed using individual lesions in a single site for up to 60 seconds in duration before discontinuing energy delivery. Proper position will be confirmed by MR imaging and/or EP signals before delivery of each lesion. The procedural endpoint will be demonstration of bidirectional block at the CTI via differential pacing maneuvers.

Study burden and risks

The VISABL-AFL investigation studies the use of a next generation ablation and diagnostic catheters, EP system, and a novel mapping system to perform RF

ablation treatment for type-1 atrial flutter in the MRI. The data is essential for understanding how the investigational device(s) perform under the clinical trial condition in this patient population, ultimately supporting market approval submissions in the EU and US.

The additional burden to the patients would be a follow up visit at 1 week and 3 months to determine adverse event and arrhythmia recurrences. Depending on the site, these visits or phone calls may be standard of care. All other pre-screening procedures would be considered standard of care for patients receiving an RF ablation procedure for their type-1 atrial flutter. The extra visits and data collection compared to standard of care will allow for closer monitoring of the patient, which is important for identifying and management potential adverse events as well as facilitation of the collection of more comprehensive data of the investigational device(s).

Non-participation in this study does not preclude patients from receiving RF ablation for their type-1 atrial flutter in the MRI as they can receive this therapy with the 1st generation catheters and EP system currently CE marked. The benefit for the patient is expected to be the same as when receiving the treatment with the currently marked released device version. The benefit of this new version relates to a behavior of the shaft to improve handling (IB 3.1.1).

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

Inclusion Criteria:
• Patient indicated for type I atrial flutter ablations with at least 1 documented episode of type I atrial flutter within 6 months (180 days) of enrollment
• Patient 18 years and older

Exclusion criteria

Exclusion criteria:
• Contraindications for MRI procedures
• Patients who cannot have anti-arrhythmic drugs (class I or class III) prescribed for the treatment of type I atrial flutter stopped prior to the procedure
• Previous CTI ablation procedures
• Myocardial infarction within 60 days of enrollment
• Current unstable angina
• Cardiac surgery within 90 days of enrollment
• Any cerebral ischemic event (including transient ischemic attacks) within 6 months (180 days) of enrollment
• Thrombocytosis or thrombocytopenia
• Contraindication to anticoagulation therapy
• Currently documented intracardiac thrombus or myxoma
• Implanted of permanent leads of an implantable device in or through the right atrium within 90 days of enrollment
• Prosthetic valve through which the catheter must pass
• Interatrial baffle or patch through which the catheter must pass
• Moderate or severe tricuspid valve regurgitation or stenosis
• Uncompensated congestive heart failure
• Active systemic infection
• Pregnancy or if subject plans to become pregnant during the trial
• Uncontrolled hyperthyroidism

• Any other significant uncontrolled or unstable medical condition
• Enrollment in any concurrent study without Imricor written approval
• Life expectancy of less than or equal to 2 years (730 days) per physician opinion

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2024
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Vision-MR Ablation Catheter 2.0;Vision-MR Ablation Cable Set 2.0;Vision-MR Diagnostic Catheter;Visio
Registration:	No

Ethics review

Approved WMO

Date:	20-03-2025
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NCT05904548
CCMO	NL87365.000.24