Vision-MR Ablation Catheter 2.0 for Treatment of Ventricular Tachycardia

Published: 28-07-2023
Last updated: 21-12-2024

The purpose of the VISABL-VT clinical investigation is to demonstrate safety and efficacy of RF ablation of ventricular tachycardia (VT) attributable to ischemic cardiomyopathy (ICM) with the Vision-MR Ablation Catheter 2.0. Data collected from this...

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

Summary

ID

NL-OMON53247

Source
ToetsingOnline

Brief title
VISABL-VT study

Condition

- Cardiac arrhythmias

Synonym
Ventricular Tachycardia; 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, Ventricular Tachycardia

Outcome measures

Primary outcome

Primary Efficacy Endpoint: Absence of inducible clinical ventricular tachycardia following the last RF application with the Vision-MR Ablation Catheter 2.0.

Acceptance Criteria: Performance goal of 80% success rate (66% lower, one-sided 95% confidence bound) for absence of inducible clinical ventricular tachycardia.

Treatment failure will be defined as any of the following:

• Inability to achieve absence of inducible clinical ventricular tachycardia solely with the Vision-MR Ablation Catheter 2.0

• The use of a market released catheter to achieve absence of inducible clinical ventricular tachycardia

• The need to terminate the procedure due to functionality of the Vision-MR Ablation Catheter 2.0

• The need to terminate the procedure due to adverse events associated with the Vision-MR Ablation Catheter 2.0

The following intercurrent events preclude evaluation of the primary efficacy endpoint:

• Procedures not initiated (defined as insertion of the investigational catheter) due to intercurrent events not associated with the Vision-MR Alation

Catheter 2.0 or accessory devices required during the ablation procedure.

• Procedures terminated early due to events not associated with the Vision-MR Ablation Catheter 2.0, for example:

o Inability to obtain transseptal access, if required

o Need for defibrillation outside of the MR Scanner Room

• Non-clinical VT remains inducible at the end of the procedure.

These intercurrent events are not considered treatment failures. In these instances, subject data will not contribute to the primary efficacy endpoint but will be included in the primary safety analysis and all other secondary and ancillary endpoints.

Primary Safety Endpoint: The primary safety endpoint is a composite of any procedure or device related serious adverse events through 7 days post index ablation procedure

Acceptance Criteria: Performance goal of 7.5% event rate (18% upper, one-sided 95% confidence bound).

Secondary outcome

Secondary Efficacy Endpoint: The secondary efficacy endpoint is chronic success defined as 6-month (180 day) freedom from recurrence of sustained VT or VT requiring intervention. and freedom from new or increased dose of Class I or III AAD at 6 months following the index ablation procedure.

• Freedom from recurrent VT will be verified via extended cardiac monitoring (e.g., 24 hr. Holter, external loop recorder, event recorder, implantable loop

recorder, or implantable cardiac device etc.) performed at the 6-month follow-up visit if VT has not been detected at prior scheduled or unscheduled follow up visit.

• Recurrent VT detected and confirmed at scheduled or unscheduled visits with a cardiac monitor (such as a 12 lead ECG, Holter monitor, event recorder, external and/or implantable cardiac monitor) between the procedure date and the 6-month follow up will count as a chronic efficacy failure.

Acceptance Criteria: Performance goal of 72% success rate (55% lower, one-sided 95% confidence bound) for freedom from recurrence of sustained VT or VT requiring intervention and freedom from new or increased dose of Class I or III AAD at 6-months post procedure.

Secondary Safety Endpoint: All serious adverse events will be collected during the study and reported as a secondary endpoint. Adverse events will be reviewed by an independent clinical events committee and adjudicated as to severity, device, and procedures relatedness

Study description

Background summary

RF ablation is a known treatment option to eliminate the electrical pathways that leads to cardiac arrhythmias such as ventricular tachycardia (VT). The key to successful ablation treatment is accurate catheter positioning at the area to receive RF therapy. In complex arrhythmias, such as VT, the ablation strategy, risks and outcomes are related to the mechanism and location of the arrhythmia. In general, a catheter ablation procedure involves identifying the

target, arrhythmia-inducing, myocardial cells; advancing an ablation catheter to the target location in the heart; and delivery energy (therapy) to destroy the target cells responsible for triggering the arrhythmia.

Current RF ablation is performed using fluoroscopy, which demonstrated success rates for idiopathic/focal VT and Structural Heart Disease (SHD) related VT ablations of 80-90% and 40-88% respectively. Problems limiting success of the procedure include inability to identify the arrhythmogenic cells as seen in idiopathic VT or scar tissue as seen after myocardial infarction for therapy or inability to access the target tissue location in the myocardium.

Identifying the precise location of the origin of the arrhythmia has been proven to be crucial to the success of ablation, particularly in structural heart related VT. This identification is often done through a combination of electroanatomical mapping techniques and pre-procedural imaging to define the substrate and identify the crucial circuit that will guide the ablation8. Recently, contrast-enhanced magnetic resonance imaging (MRI) has been used to image and map target substrate prior to catheter ablation and appears to improve procedural success. These procedures require pre-ablation MRI scans to be taken of the cardiac anatomy and then uploaded to mapping software to provide and guide during ablation procedures. Devices to perform ablation under real-time MRI are currently not approved for ventricular tachycardia procedures but are marketed for type I atrial flutter. Performing ablation under real-time MRI provides the potential to improve first-time success rates of ablation procedures by providing ablation lesion visualization and verification along with individualized ablation therapy strategy. In addition, the use of CMR-guided ablation provides the immediate benefit of a radiation free environment for patients and physicians.

MR-guided type I atrial flutter ablation procedures are performed on label in Europe with the CE marked-first generation Vision-MR Ablation Catheter and accessory devices. Multiple pre-market clinical trials and a current, on-going post-market clinical follow up study have characterized the usability and safety of type I atrial flutter ablations with the CE marked Vision-MR Ablation Catheter, and accessory devices. Bench and pre-clinical animal studies have been performed to ensure that design changes for the Vision-MR Ablation Catheter 2.0 either maintain or improve performance of the ablation catheter and allow for the maneuverability required to expand the indication of the Vision-MR Ablation Catheter 2.0 to include ventricular tachycardia. The VISABL-VT clinical investigation will demonstrate the safety and efficacy of the Vision-MR Ablation Catheter 2.0 and accessory devices for the treatment of ventricular tachycardia.

Study objective

The purpose of the VISABL-VT clinical investigation is to demonstrate safety and efficacy of RF ablation of ventricular tachycardia (VT) attributable to

ischemic cardiomyopathy (ICM) with the Vision-MR Ablation Catheter 2.0.

Data collected from this trial will be used to support EU pre-market application of the Vision-MR Ablation Catheter 2.0 for use in treatment of ventricular tachycardia patients 18 years or older. Data on the performance and safety of supportive investigational products (including the NavTrac-MR Transseptal Kit and Needle) will also be collected prospectively during this investigation and will be used to support market release of these products in Europe.

The follow-up period is 6 months.

The tests performed within the study are standard of care, limiting the risk of participating in the study for the patients.

Study design

Imricor is sponsoring the VISABL-VT clinical investigation. VISABL-VT is a prospective, single-arm, multi-center, interventional investigation of the safety and efficacy of RF ablation of ventricular tachycardia associated with ischemic cardiomyopathy performed with the Vision-MR Ablation Catheter 2.0. The investigation will be conducted in Europe. The study is financed by Imricor (the Sponsor).

The investigation will allow up to 5 roll-in subjects at each site, if necessary, to optimize the procedure workflow.

A total of 64 subjects will be enrolled in this study.

Intervention

Phase I: Set up and vascular access
Following sedation, the 12-Lead ECG electrodes, defibrillator patches, and MRI body coil are placed, including the Vision-MR Dispersive Electrode. Vascular access will be obtained for both the diagnostic and ablation catheters in the femoral vein(s) (and artery if retrograde left ventricular access is desired).

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 (iSuite or NorthStar). Perform LGE enhanced 3D images of the left ventricle for substrate mapping (ADAS). Import 3D scans into image guidance software (iSuite or NorthStar) to visualize the LV fibrotic substrate and guide procedure planning. Insert and advance the Imricor Vision-MR Diagnostic Catheter into the right ventricular apex (RVA).Advance the Imricor Vision-MR Ablation Catheter 2.0 to the left ventricle (LV) (either transeptally or retrograde approach). Induce VT

prior to ablation of target tissues (can be skipped based on patient hemodynamic stability and physician discretion). If VT is induced, the TeslaSX1 MR compatible defibrillator may be used to return the patient to sinus rhythm. The physician will navigate the ablation catheter to desired ablation target location(s) identified via the substrate 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 catheter position will be confirmed by mapping, MR imaging and/or EP signals before delivery of each lesion.
The procedural endpoint will be demonstration of non-inducibility of clinical ventricular tachycardia after the final radiofrequency application (mark this inducement time point in Advantage-EP system). Perform post procedural T2W imaging of lesions.
If the electrophysiological endpoint, non-inducibility of clinical ventricular tachycardia, is not achieved in the MR environment, the subject may be transferred from the MR suite to a conventional electrophysiology lab to complete the procedure.

Study burden and risks

Most of the risks associated with conventional ventricular tachycardia ablation are the same for patients participating in the study. Risks associated with complications may be reduced as described. Additionally, risks associated with unseen anatomical features may also be reduced. Finally, risks associated with ionizing radiation exposure may be reduced or eliminated.

The purpose of this clinical study is to evaluate the safety and efficacy of RF ablation of ventricular tachycardia attributed to ischemic cardiomyopathy with Imricor*s Vision-MR Ablation Catheter 2.0. The Vision-MR Ablation Catheter 2.0 and accessory devices used in this investigation are modeled after currently manufactured and marketed RF ablation catheters and accessory devices indicated for ventricular tachycardia. Catheter ablation for ventricular tachycardia has anticipated risks as it is an invasive procedure requiring sedation or anesthesia. Therefore, adverse events associated with anesthesiologic procedures may be experienced (e.g., anesthesia complications, injury, infections, bleeding, exacerbation of pre-existing conditions, healing, and complications, etc.). In addition, there are anticipated risks due to the use, performance, and/or presence of the devices similar to those to be investigated in the study.

Performing a MRI scan in patients carrying an ICD, may cause heating of the ICD and even burns. To prevent this, maximum SAR limits (specific absorption rate (measured in Watt/kg) and B1+rms limits as specified by the ICD manufacturer) will not be exceeded. This is according to best practice. The fast tracking sequence that is used to navigate the catheters will continuously be monitored to guarantee safety.
Additionally, there are risks to patients participating in the study associated

with the procedure being performed in a less familiar environment (MR lab instead of x-ray) and MR device safety concerns. With regard to the environment, significant effort has gone into creating an interventional environment that is as similar to the conventional x-ray environment as possible. The position of the operating electrophysiologist relative to the patient is the same as in the x-ray lab and the responsibilities of support staff are substantially equivalent (patient monitoring, stimulator operation, ablation generator operation, etc.). Lastly, if the procedure is not able to be completed in the MR lab the subject may be transferred from the MR suite to a conventional electrophysiology lab to complete the procedure. Details of the transfer from the MR environment to the conventional electrophysiology lab are worked out with each site during site initiation.

The investigational devices were developed and tested to be MR conditional and function as intended in the MR environment. Investigational products or components that are non-MR conditional are labeled as such and kept isolated from the magnet room. Risk to the subject due to interactions within the MR environment on investigational devices is not anticipated, but any adverse events associated with the MR environment will be collected. Subjects with non-MR conditional implantable devices or other contraindications to MRI will be excluded from this investigation.
Treatment required for procedure and/or device related adverse events that are experienced might include medication, or other surgical and medical remedies. Potential adverse events related to the Vision-MR Ablation Catheter 2.0 for the treatment of ventricular tachycardia are as described earlier.

There is no guaranteed benefit to participating in this investigation, however all the benefits associated with conventional ventricular tachycardia ablation hold true for patients participating in this study. The ablation procedure performed in the study is unchanged from a conventional ablation procedure, only the environment is different (MR lab versus conventional x-ray lab).

The investigational devices were designed to be substantially equivalent to existing conventional devices, with the added characteristic of being safe for use in the MR environment. The Vision-MR Ablation Catheter 2.0 looks, feels, and performs like conventional ablation catheters. The MRI compatible image guidance software, when used with a compatible EP recording system, provides substantially the same information, functionality, and interface as a conventional mapping system.

The additional benefits to a patient participating in the study are improved soft tissue imaging capabilities delivered by the MR imaging, and the elimination of ionizing radiation.

X-ray imaging provides little to no soft tissue visualization, meaning that cardiac tissues are nearly invisible. MR imaging allows the electrophysiologist to see the cardiac tissue clearly and identify anatomical features that cannot

be identified in the x-ray lab. Seeing such features may be beneficial to the efficiency and effectiveness of the ablation procedure. An example of this is the occasional existence of tissue pouch along the CTI. With MR imaging, the operator can see this feature and may be able to tailor his approach to creating a complete ablation line, accounting for the pouch. In the x-ray lab, such as pouch likely go undetected and may complicate or prolong the ablation procedure.
Improved visualization of cardiac tissue may also reduce complications, such as perforation since tissue boundaries can be seen with MR imaging. In addition, if a complication does occur, MR imaging may allow the complication to be more quickly identified and corrective measures to be more quickly taken.

Participants in the study may also receive reduced or eliminated exposure to ionizing radiation. While ventricular tachycardia ablation is not associated with massive doses of x-ray radiation, significant doses are used. This is especially true for those patients who have anatomical features that are undetectable with x-ray imaging since these procedures may take longer to complete. In addition, patients may require several ablation procedures throughout their lifetimes, and the radiation dose for all these potential procedures is cumulative. Therefore, reducing or eliminating the ionizing radiation dose in this study has the benefit or reducing the short-term and long-term potential implications of radiation exposure for both the patient and operator.

Contacts

Public
Imricor Medical Systems, Inc

Gateway Blvd 400
Burnsville 55337 MN
US
Scientific
Imricor Medical Systems, Inc

Gateway Blvd 400
Burnsville 55337 MN
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion Criteria
• Documented (ECG/EGM) spontaneous episode of sustained ventricular tachycardia within 6 months
• Diagnosis of ischemic cardiomyopathy
• AAD therapy refractory, contraindicated, not tolerated, or not desired
• 18 years or older

Exclusion criteria

Exclusion Criteria • Implanted with non-MR compatible medical devices or contraindicated for an MRI • Presence of intracardiac thrombus (verified via CT/MRI/TEE/TTE within 48 hours of procedure - or at start of procedure) • Thrombocytopenia or coagulopathy • Mechanical mitral and/or aortic valve precluding access to the left ventricle • Severe aortic stenosis • Myocardial infarction requiring stent implantation within 90 days of procedure • Previous cardiac surgery within 60 days of procedures • Class IV Heart Failure • EF < 25% • Patients with a glomerular filtration rate (GFR) < 30 • Women who are pregnant • Life expectancy < 12 months • Enrollment in another study without Imricor approval

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2023
Enrollment:	45
Type:	Anticipated

Medical products/devices used

Generic name:	Vision-MR Ablation Catheters 2.0 and console;TeslaSX1 MR Compatible Defibrillator;iSUITE Mapping Sof
Registration:	No

Ethics review

Approved WMO

Date:	28-07-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	25-03-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	14-10-2024
Application type:	Amendment
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	NL84094.000.23