Cryoablation for Monomorphic Ventricular Tachycardia

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The objective of this clinical study is to evaluate the safety and performance of the Adagio VT Cryoablation System in the ablation treatment of Monomorphic VT

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

Summary

ID

NL-OMON54426

Source
ToetsingOnline

Brief title
CryoCure VT

Condition

- Cardiac arrhythmias

Synonym
Ventricular tachycardia; fast abnormal heart rate

Research involving
Human

Sponsors and support

Primary sponsor: Adagio Medical
Source(s) of monetary or material Support: Industry; Adagio Medical

Intervention

Keyword: Cryoablation, Pre-market, Ventricular Tachycardia (VT)

Outcome measures

Primary outcome

The Primary Endpoint for Safety is an analysis of the proportion of subjects who are free from definite or probable device/procedure related Major Adverse Events (MAEs) that occur during or within 30 days following the cryoablation procedure.

The Primary Endpoint for Clinical Performance is an analysis of the proportion of patients receiving a single cryoablation procedure with freedom from ventricular tachycardia lasting longer than 30 seconds or appropriate ICD intervention until the end of the 6 month follow up period.

The Primary Endpoint for Procedure Performance is an analysis of the proportion of subjects with non-inducible clinical monomorphic VT at the conclusion of the initial cryoablation procedure.

Secondary outcome

Safety

- The proportion of study subjects with probable or definite device or procedure related serious adverse events (SAEs) including MAEs as described above, or serious adverse device effects (SADEs) between 30-days and up to 12 months post-procedure.

Events will be adjudicated by an independent Data and Safety Monitoring Board (DSMB) for relatedness to the Adagio System.

Performance

- The proportion of study subjects with non-inducible sustained monomorphic VT at the end of the ablation procedure
- The proportion of study subjects with freedom from Ventricular Tachycardia lasting longer than 30 seconds at 12 months without the use of anti-arrhythmic drugs (AADs)
- The proportion of study subjects with freedom from Ventricular Tachycardia lasting longer than 30 seconds at 12 months with previously failed AADs
- Reduction of VT burden at 6 and 12 months

Descriptive Statistics

- Procedure fluoroscopy time
- Total ablation time
- Total procedure time
- Number and location of cryoablation lesions
- Number of inducible clinical VTs before and after cryoablation
- Number of appropriate and inappropriate ICD therapies (shocks and antitachycardia pacing, ATP) in the follow up period
- Mapping and ablation strategies utilized during the ablation procedure
- Freedom from cardiovascular (CV) hospitalizations or CV-related ER visits through 12 months
- Recording of the use of AADs in the follow up period

Study description

Background summary

Ventricular tachycardia may impair cardiac output with consequent hypotension, collapse, and acute cardiac failure. The presence of pre-existing poor ventricular function is strongly associated with cardiovascular compromise. The field of catheter ablation has progressed with the development of new methods and tools, and with the publication of large clinical trials. The HRS document was used to develop this protocol and to provide the best possible outcomes for patients with ventricular arrhythmias. Catheter ablation has an important role in reducing or preventing VAs both in patients with heart disease and in those with idiopathic VTs. Once the substrate is identified, one needs an ablation source that can provide enough energy to eradicate the source of the VT. The literature shows that ventricular tachycardia ablation has proven safe and viable for most VT.
Catheter radiofrequency ablation of VT originating from the left ventricle*s papillary muscles has been linked to conflicting outcomes. Cryoablation was correlated with greater success rates and smaller recurrence rates than radiofrequency procedures, superior catheter support, and smaller frequency of polymorphic arrhythmias.
Cryoablation is a process that uses extreme cold to destroy tissue. Historically cryo in the cardiac ablation space has been used for atrial fibrillation. Adagio Medical has a history of developing cryo technology for persistent Atrial fibrillation with CE mark approval obtained in June 2020. Adagio Medical has also designed a VT catheter to prove intramural lesions for monomorphic VT

Study objective

The objective of this clinical study is to evaluate the safety and performance of the Adagio VT Cryoablation System in the ablation treatment of Monomorphic VT

Study design

A prospective, single-arm, multi-center, pre-market, clinical study designed to provide safety and performance data regarding the use of the Adagio Medical VT Cryoablation System in the treatment of ventricular tachycardia.

Intervention

A VT ablation procedure is performed by finding the abnormal ventricular heart tissue that is causing the VT and applying energy with an ablation catheter to the area. The goal is to apply energy to create a scar or destroy the tissue

that causes the VT, such that VT is no longer present or inducible.

Study burden and risks

Not applicable with this protocol

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

IC 1 Male or female the ages of >= 18 years
IC 2 Eligible for a catheter ablation due to Ischemic and/or non-ischemic recurrent symptomatic sustained monomorphic Ventricular Tachycardia also defined as having a similar QRS configuration from beat to beat.
IC 3 Has or will be receiving an ICD prior to hospital discharge post procedure.

IC 4 Refractory to at least one AAD (Refractory is defined as an AAD not able to treat the arrhythmia satisfactorily or induces unwanted side effects).
IC 5 Subject has LVEF > 20%, confirmed by echo or comparable technique in the previous 3 months or during baseline evaluation
IC 6 Willingness, ability, and commitment to participate in baseline and follow-up evaluations for the full length of the study
IC 7 Willingness and ability to give an informed consent

Exclusion criteria

EC 1 Any known objective contraindication to ventricular tachycardia ablation, TEE, or anticoagulation, including but not limited to the identification of any cardiac thrombus or evidence of sepsis
EC 2 Any duration of continuous arrythmia that is not monomorphic ventricular tachycardia. Multiple monomorphic tachycardia is acceptable, but polymorphic VT is not.
EC 3 Any VT ablation within 4 weeks prior to enrollment
EC 4 More than one prior (>4 weeks) Ventricular Tachycardia ablation or prior surgical treatment for ventricular tachycardia
EC 5 Ventricular tachycardia secondary to electrolyte imbalance, active thyroid disease, or any other reversible or non-cardiac cause
EC 6 Structural heart disease as described below:
a. Class IV heart failure
b. Aortic aneurysm
c. Previous cardiac surgery or percutaneous coronary intervention within 60 days prior to the procedure
d. Interatrial baffle, closure device, patch, or PFO occlusion device
e. IVC filter
f. Coronary artery bypass graft (CABG) procedure within six (6) months prior to the ablation procedure
g. Severe Mitral or Aortic insufficiency or stenosis based on most recent TTE
h. Cardiac myxoma
i. Significant congenital anomaly
j. Recent Myocardial Infarct (MI) or unstable angina, within 60 days prior to the ablation procedure
k. Mechanical aortic or mitral valve
EC 7 Any previous history of cryoglobulinemia
EC 8 History of blood clotting or bleeding disease
EC 9 Any prior history of documented cerebral vascular accident (CVA), TIA or systemic embolism (excluding a post-operative Deep Vein Thrombosis, DVT), within 6 months prior to the ablation procedure.
EC 10 Breastfeeding, pregnant, or anticipated pregnancy during study follow-up
EC 11 Current enrollment in any other study protocol where testing or results from that study may interfere with the procedure or outcome measurements for this study

EC 12 Any other condition that, in the judgment of the investigator, makes the patient a poor candidate for this procedure, the study or compliance with the protocol (includes vulnerable patient population, mental illness, addictive disease, candidate for heart transplantation, patient with ventricular assist device, or terminal illness with a life expectancy less than 12 months)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	27-05-2021
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Adagio Medical VT Cryoablation System
Registration:	No

Ethics review

Approved WMO Date:	21-05-2021
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	21-07-2022

Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-01-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-07-2023
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
CCMO	NL76264.100.20