Cryoablation for Monomorphic Ventricular Tachycardia (VTS)

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* IC 1 Male or female ≥ 18 years * IC 2 Patients with a clinical indication for catheter ablation due to ischemic and/or non-ischemic heart disease and recurrent symptomatic sustained scar-mediated monomorphic Ventricular Tachycardia. * IC 3 Any of the following: * Ischemic cardiomyopapthy (ICM) patients with prior history of myocardial infarction with Q waves, focal wall motion abnormality on imaging, fixed perfusion defect correlating with coronary stenosis or prior coronary intervention, 20% ≤ LVEF \< 50%. * non-ischemic cardiomyopathy (NICM) patients with scar in a territory without coronary stenosis as evidenced by CMR imaging within the prior 90 days or intra-procedurally using EAM and PES prior to investigational device use, 20% ≤ LVEF \< 50% * Arrhythmogenic right ventricular cardiomyopathy (ARVC) * IC 4 Has received a market-released ICD prior to enrollment * IC 5 Patient has had at least 1 documented spontaneous episode of SMVT within the previous 6 months * IC 6 Refractory to, or intolerant of, at least one Class III AAD. (Refractory or intolerant defined as AAD failure due to recurrent VT, not tolerated/ desired due to side effects) * IC 7 Willingness, ability, and commitment to participate in baseline and follow-up evaluations for the full length of the study * IC 8 Willingness and ability to give an informed consent

---

Exclusion Criteria:

* EC 1 Intracardiac thrombus by TTE or TEE within 48 hours prior to the procedure * EC 2 Presence of isolated epicardial scar(s) requiring epicardial ablation identified by either preoperative CMR imaging within 90 days of procedure or intra-procedurally using EAM and PES prior to investigational device use * EC 3 VTs due to any of the following causes: 1. Idiopathic VT 2. Automaticity or triggered activity 3. Bundle Branch Reentry (BBR) 4. Any focal tachycardia (e.g., papillary, RVOT) 5. Ventricular tachycardia secondary to electrolyte imbalance, active thyroid disease, or any other reversible or non-cardiac cause * EC 4 NICM patients only, if any of the following apply: 1. Congenital condition that limits access to the left or right ventricles 2. Severe aortic or mitral stenosis, severe mitral regurgitation, or severe aortic insufficiency 3. Active inflammatory processes (e.g., myocarditis) within the past 120 days 4. Sarcoidosis 5. Hypertrophic cardiomyopathy 6. Drug- or alcohol-induced cardiomyopathy * EC 5 Any VT ablation within 4 weeks prior to enrollment * EC 6 More than one prior (\>4 weeks) VT ablation or prior surgical treatment for VT within the past 2 years * EC 7 Cardiogenic shock, unless it is due to incessant monomorphic VT * EC 8 Any other cardiovascular conditions as described below: 1. Class IV heart failure 2. Aortic aneurysm 3. Previous cardiac surgery or percutaneous coronary intervention within 60 days prior to index procedure 4. Interatrial baffle, closure device, patch, or PFO occlusion device 5. Coronary artery bypass graft (CABG) procedure within six (6) months prior to the ablation procedure 6. Acute MI or unstable angina in the previous 60 days 7. Mechanical mitral or aortic valve 8. Cardiac myxoma 9. Significant congenital heart disease * EC 9 Acute illness or active systemic infection * EC 10 Any previous history of cryoglobulinemia * EC 11 History of blood clotting or bleeding disease * EC 12 Peripheral vascular disease that precludes LV access * EC 13 Contraindication to heparin * EC 14 Allergy to radiographic contrast dye that cannot be medically managed prior to the ablation procedure * EC 15 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 16 Pregnant, or anticipated pregnancy during study follow-up * EC 17 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 18 Any other condition (e.g., ARVC with extensive free wall scarring) 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)

Conditions & Interventions

Interventions:
DEVICE: Ultra Low Temperature Ablation (ULTA)
Conditions:
Ventricular Tachycardia, Sustained, Ventricular Tachycardia, Monomorphic
Keywords:
cryoablation, monomorphic VT, sustained monomorphic VT, Ultra Low Temperature Ablation, ULTA

More Information

Contact(s): Nabil Jubran, MS - njubran@adagiomedical.com
Principal Investigator:
IRB
Number:
System ID: NCT07650032
