HEAL-IST IDE Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Age ≥ 18 years and ≤ 75 years at time of enrollment consent 2. Subject has a diagnosis of IST 3. Documentation of refractoriness (intolerance or failure) of a drug (e.g., rate control drugs such as beta-blockers/calcium channel blockers, ivabradine), and/or AADs 4. Subject is willing and able to provide written informed consent

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Exclusion Criteria:

1. Subjects on whom cardiac surgery or single lung ventilation cannot be performed 2. Subjects with indication for or existing ICDs/Pacemakers 3. Presence of channelopathies 4. Previous cardio-thoracic surgery 5. Left Ventricular Ejection Fraction (LVEF) \< 50% 6. Body Mass Index (BMI) ≥ 35 7. Presence of supraventricular or ventricular tachycardia 8. Presence of Postural Orthostatic Sinus Tachycardia (POTS) 9. Presence of congenital heart disease 10. History suggestive of secondary cause of tachycardia such as pheochromocytoma, anemia, thyrotoxicosis, chronic fever of unknown origin, COPD, long-term bronchodilators use, severe asthma or carcinoid syndrome 11. Subjects who have had a previous catheter ablation in the right atrium for IST or other disorders 12. Life expectancy \< 24 months 13. Pregnant or planning to become pregnant during trial 14. Subjects with substance abuse 15. Subjects with previous weight loss surgery 16. Subject is unwilling and/or unable to return for scheduled follow-up visits 17. Current participation in another clinical investigation of a medical device or a drug, or recent participation in such a trial that may interfere with trial results 18. Not competent to legally represent him or herself (e.g., requires a guardian or caretaker as a legal representative) and; 19. 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 investigation or to comply with follow-up requirements, or impact the scientific soundness of the clinical investigation results

Conditions & Interventions

Interventions:
DEVICE: AtriCure ISOLATOR Synergy Surgical Ablation System
Conditions:
Inappropriate Sinus Tachycardia

More Information

Contact(s): Joseph Derr - jderr@atricure.com
Principal Investigator:
Phase: NA
IRB
Number:
System ID: NCT05280093
