

Endocardial Mapping With the CoreMap EP Mapping System

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Subject has persistent or long-standing persistent AF, at the discretion of the investigator (Phase 1 & 2) 2. Subject has PerAF with no history of prior AF ablation therapy (Phase 3) 3. Subject is 18 to 80 years of age 4. Subject has presence of AF-related symptoms and is scheduled for clinically indicated standard of care AF ablation to manage PerAF (Phase 2 or 3) or long-standing PerAF (Phase 2) 5. Subject is able to provide written informed consent 6. Subject is able and willing to complete all study procedures

Exclusion Criteria:

1. Any of the following within three months of enrollment: 1. Myocardial infarction (MI) 2. Any surgical or percutaneous cardiac procedure including coronary intervention and cardiac ablation 3. Confirmed thrombus on imaging 2. Any of the following within six months of enrollment: 1. Cardiac surgery including coronary artery bypass grafting, ventriculotomy, atriotomy 2. Thromboembolic event (stroke) 3. Any of the following cardiac conditions: 1. New York Heart Association (NYHA) IV 2. Left ventricular ejection fraction (LVEF) $\leq 30\%$ 3. Left atrial diameter $\geq 55\text{mm}$ (anterioposterior) (Phase 3) 4. Carotid stenting or endarterectomy 5. Atrial or ventricular septal closure or left atrial appendage closure 6. Implanted permanent pacemaker, biventricular pacemaker, or any type of implantable cardiac defibrillator; loop recorders are permitted. 7. Presence of intramural thrombus, tumor (including atrial myxoma), or other abnormality that precludes vascular access, catheter introduction, or manipulation 8. Unstable angina 9. Prior mitral or tricuspid valve surgery, repair, prosthetic or mechanical valve 10. Moderate to severe mitral valve stenosis or other severe valvular disease 11. Any blood clotting or bleeding abnormalities 4. Contraindication to systemic anticoagulation 5. AF secondary to electrolyte imbalance, acute alcohol intoxication, or reversible or non-cardiac cause 6. Body mass index (BMI) $\geq 40 \text{ kg/m}^2$ 7. Severe pulmonary disease, pulmonary hypertension, or any chronic respiratory condition 8. Renal failure requiring dialysis or transplant 9. Acute illness, active systemic infection, or sepsis 10. Active drug or alcohol dependency 11. Hypertrophic cardiomyopathy or cardiac amyloidosis 12. Cor pulmonale 13. Any contra-indication that may extend procedure time, at the discretion of the operator 14. Any woman known to be pregnant or breastfeeding, or any woman of childbearing potential who is not on a reliable form of birth regulation method or abstinence 15. Subject considered part of vulnerable population 16. Life expectancy less than one year 17. Employee of the study site or Sponsor 18. Subjects who are currently enrolled in another study that would directly interfere with this study

Conditions & Interventions

Interventions:

DEVICE: CoreMap EP Mapping System Mapping, DEVICE: CoreMap EP Mapping System Map-Guided Ablation

Conditions:

Persistent Atrial Fibrillation

More Information

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Principal Investigator:

IRB

Number:

System ID: NCT06529978

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