A Study of the TactiFlex SE Catheter and Volt PFA Generator in Subjects With PAF:

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Documented symptomatic paroxysmal atrial fibrillation (PAF). Documentation requirements are as follows: 1. Physician's note indicating recurrent self-terminating AF with ≥ 2 episodes of PAF within the 6 months prior to enrollment AND 2. One electrocardiographically documented PAF episode within 12 months prior to enrollment. NOTE: Documented evidence of the AF episode must either be continuous AF on a 12-lead ECG or include at least 30 seconds of continuous AF from another ECG device. 2. Plans to undergo a catheter ablation procedure due to symptomatic PAF and is refractory, intolerant, or contraindicated to at least one Class I-IV AAD medication 3. At least 18 years of age 4. Able and willing to comply with all trial requirements including pre- procedure, post-procedure, and follow-up testing and requirements 5. Informed of the nature of the trial, agreed to its provisions, and has provided written informed consent as approved by the Institutional Review Board/Ethics Committee (IRB/EC) of the respective clinical trial site.

Exclusion Criteria:

1. Previously diagnosed persistent or long-standing persistent atrial fibrillation (Continuous AF greater than 1 year in duration) 2. Arrhythmia due to reversible causes including thyroid disorders, acute alcohol intoxication, electrolyte imbalance, severe untreated sleep apnea, and other major surgical procedures in the preceding 90 days 3. Known presence of cardiac thrombus 4. Left atrial diameter (LAD) \> or equal to 5.0 cm (anteroposterior diameter) within 180 days prior to the index procedure 5. Left ventricular ejection fraction (LVEF) \< or equal to 35% as assessed with echocardiography or computerized tomography (CT) within 180 days prior to the index procedure 6. New York Heart Association (NYHA) class III or IV heart failure 7. Body mass index \> or equal to 40 kg/m2 8. Pregnant or nursing 9. Patients who have had a ventriculotomy or atriotomy within the preceding 28 days of procedure 10. Myocardial infarction (MI), acute coronary syndrome, percutaneous coronary intervention (PCI), or valve or coronary bypass grafting surgery within preceding 90 days 11. Stroke or TIA (transient ischemic attack) within the last 90 days 12. Heart disease in which corrective surgery is anticipated within 180 days after procedure 13. History of blood clotting or bleeding abnormalities including thrombocytosis, thrombocytopenia, bleeding diathesis, or suspected anti- coagulant state 14. Contraindication to long-term anti-thromboembolic therapy 15. Patient unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation 16. Known sensitivity to contrast media (if needed during the procedure) that cannot be controlled with pre-medication 17. Previous left atrial surgical or left atrial catheter ablation procedure (including left atrial appendage (LAA) closure device) 18. Plans to have an LAA closure device implanted during the follow-up period 19. Presence of any condition that precludes appropriate vascular access 20. Severe mitral regurgitation (regurgitant volume ≥ 60 mL/beat, regurgitant fraction ≥ 50%, and/or effective regurgitant orifice area ≥ 0.40cm2) 21. Previous tricuspid or mitral valve replacement or repair 22. Patients with prosthetic valves 23. Patients with a myxoma 24. Patients with an interatrial baffle or patch as the transseptal puncture could persist and produce an iatrogenic atrial shunt 25. Stent, constriction, or stenosis in a pulmonary vein 26. Rheumatic heart disease 27. Hypertrophic cardiomyopathy 28. Active systemic infection 29. Renal failure requiring dialysis 30. Severe pulmonary disease (e.g., restrictive pulmonary disease, constrictive or chronic obstructive pulmonary disease) or any other disease or malfunction of the lungs or respiratory system that produces severe chronic symptoms 31. Presence of an implantable therapeutic cardiac device including permanent pacemaker, biventricular pacemaker, or any type of implantable cardiac defibrillator (with or without biventricular pacing function) or planned implant of such a device for any time during the follow-up period. Presence of an implantable loop recorder is acceptable as long as it is removed prior to insertion of the investigational device. 32. Patient is currently participating in another clinical trial or has participated in a clinical trial within 30 days prior to screening that may interfere with this clinical trial without pre-approval from this study Sponsor 33. Unlikely to survive the protocol follow up period of 12 months 34. Presence of other medical, anatomic, comorbid, 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. 35. Individuals without legal authority 36. Individuals unable to read or write

Conditions & Interventions

Interventions:
DEVICE: PFA Ablation catheter
Conditions:
Atrial Fibrillation (AF), Atrial Arrhythmia, Paroxysmal AF, Drug Refractory Paroxysmal Atrial Fibrillation
Keywords:
Symptomatic, recurrent, drug refractory PAF, Atrial Fibrillation, Paroxysmal AF, Pulsed Field Ablation, Radio Frequency, PFA

More Information

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Phase: NA
IRB
Number:
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