A Study of Assessment on Safety and Effectiveness of BWI Pulsed Field Ablation With OMNYPULSE Catheter for the Treatment of Paroxysmal Atrial Fibrillation (PAF)

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Diagnosed with symptomatic paroxysmal AF with: 1. At least two symptomatic AF episodes within last six months from enrollment 2. At least one electrocardiographically documented AF episode within twelve months prior to enrollment * Failed at least one Class I or Class III antiarrhythmic drug * Willing and capable to provide consent * Able and willing to comply with all pre-, post- and follow-up testing and requirements

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Exclusion Criteria:

* Previously diagnosed with persistent AF (greater than \[\>\] 7 days in duration) * AF secondary to electrolyte imbalance, thyroid disease, or reversible or non-cardiac cause. * Previous surgical or catheter ablation for AF * Patients known to require ablation outside the PV ostia and outside the CTI region. * Documented severe dilatation of the left atrium (LAD\>50 mm) antero-posterior diameter on imaging within 6 months prior to enrollment * Documented left atrium (LA) thrombus by imaging within 48 hours of the procedure * Documented severely compromised left ventricular ejection fraction (LVEF \<40%) by imaging within 6 months prior to enrollment * Uncontrolled heart failure or New York Heart Association (NYHA) Class III or IV * History of blood clotting, bleeding abnormalities or contraindication to anticoagulation (heparin, warfarin, or dabigatran) * Documented thromboembolic event (including transient ischemic attack or TIA) within the past 6 months * Previous Percutaneous Coronary Intervention (PCI)/ myocardial infarction \[MI\] within the past 2 months * Coronary Artery Bypass Grafting (CABG) surgery within the past 6 months * Valvular cardiac surgical/percutaneous procedure * Unstable angina within 6 months * Anticipated cardiac transplantation, cardiac surgery, or other major surgery within the next 12 months * Significant pulmonary disease or any other disease or malfunction of the lungs or respiratory system that produces severe chronic symptoms * Significant congenital anomaly or medical problem that in the opinion of the investigator would preclude enrollment in this study * Prior diagnosis of pulmonary vein stenosis * Pre-existing hemi diaphragmatic paralysis * Acute illness, active systemic infection, or sepsis * Presence of intracardiac thrombus, myxoma, tumor, interatrial baffle or patch or other abnormality that precludes catheter introduction or manipulation * Severe mitral regurgitation * Presence of an implanted pacemaker or Implantable Cardioverter-Defibrillator (ICD) or other implanted metal cardiac device (other than coronary stents) that may interfere with the PF energy field) * Presence of a condition that precludes vascular access * Current enrollment in an investigational study evaluating another device or drug * Women who are pregnant (as evidenced by pregnancy test if pre-menopausal), lactating, or who are of child-bearing age and plan on becoming pregnant during the course of the clinical investigation * Life expectancy less than 12 months * Presenting contra-indications for the devices used in the study, as indicated in the respective Instructions for Use (IFU)

Conditions & Interventions

Interventions:
DEVICE: OMNYPULSE™ Catheter with the TRUPULSE Generator
Conditions:
Atrial Fibrillation

More Information

Contact(s): Study Contact - rshar120@its.jnj.com
Principal Investigator:
Phase: NA
IRB
Number:
System ID: NCT06455098
