Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Eighteen (18) years of age or older * Despite medical therapy, per the local Heart Team, patient has signs of TR, symptoms from TR, or prior heart failure hospitalization from TR. * Severe or greater tricuspid regurgitation * New York Heart Association (NYHA) Class II-IVa or heart failure hospitalization in the prior 12 months * Patient is at an intermediate or greater estimated risk of mortality with tricuspid valve surgery as determined by the cardiac surgeon with concurrence by the local Heart Team * Patient is able and willing to give informed consent, follow protocol procedures, and comply with follow-up visit requirements

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Exclusion Criteria:

* Tricuspid valve anatomy not evaluable by TTE or TEE * Tricuspid valve anatomy precludes proper device deployment and function * Patient with refractory heart failure requiring, advanced intervention (i.e. patient has or will need left ventricular assist device, or transplantation) (ACC/AHA Stage D heart failure) * Presence of trans-tricuspid pacemaker or defibrillator leads which meet one of the following: 1. Would prevent proper TR reduction due to interaction of the lead with the leaflets 2. Were implanted in the RV within the last 90 days prior to the point of enrollment * Primary non-degenerative tricuspid disease * Previous tricuspid valve repair or replacement that would interfere with placement of PASCAL * Clinically significant, untreated coronary artery disease requiring revascularization, unstable angina, evidence of acute coronary syndrome, recent myocardial infarction * Significant intra-cardiac mass, thrombus, or vegetation per echo core lab assessment * Deep vein thrombosis (DVT) or pulmonary embolism (PE) in the last 90 days * Recent Stroke * Active gastrointestinal (GI) bleeding * Presence of infiltrative cardiomyopathy or valvulopathy (including carcinoid, amyloidosis, sarcoidosis, hemochromatosis) or significant congenital heart disease, including but not limited to atrial septal defect, RV dysplasia, and arrhythmogenic RV * Need for emergent or urgent surgery for any reason, any planned cardiac surgery within the next 12 months (365 days), or any planned percutaneous cardiac procedure within the next 90 days * Any of the following cardiovascular procedures: 1. Percutaneous coronary, intracardiac, or endovascular intervention within the last 30 days prior to the point of enrollment 2. Carotid surgery within 30 days prior to the point of enrollment 3. Direct current cardioversion within the last 30 days prior to the point of enrollment 4. Leadless RV pacemaker implant within the last 30 days prior to the point of enrollment 5. Cardiac surgery within 90 days prior to the point of enrollment * Severe aortic, mitral and/or pulmonic valve stenosis and/or regurgitation * Known history of untreated severe symptomatic carotid stenosis or asymptomatic carotid stenosis * Active endocarditis within the last 90 days or infection requiring antibiotic therapy within the last 14 days * Patient is oxygen-dependent or requires continuous home oxygen * Pregnant, breastfeeding, or planning pregnancy within the next 12 months (365 days) * Concurrent medical condition with a life expectancy of less than 12 months in the judgment of the Investigator * Patient is currently participating in another investigational biologic, drug, or device clinical study * Patient has other medical, social, or psychological conditions that preclude appropriate consent and follow-up, or the patient is under guardianship * Any patient considered to be vulnerable

Conditions & Interventions

Interventions:
DEVICE: Edwards PASCAL System, DRUG: Optimal Medical Therapy, DEVICE: Edwards PASCAL System, DEVICE: Edwards PASCAL System
Conditions:
Tricuspid Regurgitation, Tricuspid Valve Insufficiency, Tricuspid Valve Disease

More Information

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Phase: NA
IRB
Number: HM20023593
System ID: NCT04097145
