An Early Feasibility Study Assessing Treatment of Pulmonary Arterial Hypertension Using the Aria CV Pulmonary Hypertension System (ASPIRE PH)

Status: Recruiting

Eligibility Criteria

Sex: All
Age Group: 18 years and over
Common

Inclusion Criteria:

18 years of age or older. Mean pulmonary artery pressure (mPAP) > 25mmHg. Right heart dysfunction as evidence by at least one of the following: Tricuspid Annulus Plan Systolic Excursion (TAPSE) ≤ 16mm RV Fractional area change < 35% RV systolic velocity < 11.5 cm/s RV free wall strain < 18% Lateral tricuspid annulus peak systolic velocity (S') < 9cm/s Pulmonary compliance (C) < 3.0 ml/mmHg Current assessment of WHO FC III or ambulatory IV Main pulmonary artery (MPA) diameter and anatomy suitable for placement of the device as defined in the Instructions For Use (IFU) and as assessed by multi-slice computed tomography (MSCT). Subject is deemed appropriate for Aria CV device by the Subject Care Team at the investigation site and approved by the Eligibility Review Committee (ERC). The subject has agreed to participate in the study by signing the study specific informed consent form. The subject agrees to abide by device related travel restrictions. Unique Inclusion Criteria for WHO Group I: Pulmonary capillary wedge pressure (PCWP) ≤ 15mmHg Pulmonary vascular resistance (PVR) > 3 Woods Units (WU) The subject remains symptomatic despite being on a stable drug regimen of PH specific medication(s) appropriate for their PH classification for at least 90 days prior to planned index procedure. Unique Inclusion Criteria for WHO Group II: 10. Previous diagnosis of heart failure with preserved ejection fraction (HFpEF) (ejection fraction ≥ 50%) 11. PCWP > 15 mmHg 12. PVR > 3 WU Unique Inclusion Criteria for WHO Group III: 10. Previous diagnosis of lung disease, including but not limited to chronic obstructive pulmonary disease (COPD) or interstitial lung disease (ILD) including idiopathic pulmonary fibrosis (IPF) or combined emphysema with fibrosis. 11. PCWP ≤ 15mmHg 12. PVR >4 WU Common

Exclusion Criteria:

Diagnosis of WHO Groups 4 or 5 PH. Recent clinical event(s) of any of the following: Myocardial infarction or stroke within 6 months prior to the index procedure; Sustained tachyarrhythmia (documented heart rate >110/min) within 2 months prior to the index procedure; Uncontrolled, chronic atrial fibrillation. Pre-existing or requirement of emergent surgery/ intervention, or implantation of prosthetic cardiac device that, in the opinion of the investigator, may interfere with Aria CV PH System placement or function. Any of the following medical history or comorbidities: a. History of endocarditis; b. History of unprovoked Pulmonary Embolism; c. Current renal insufficiency as demonstrated by an eGFR < 30 mL/min/1.73 m2 or end stage renal disease requiring chronic dialysis; d. Current diagnosis of scleroderma associated with: i. Any history of GI bleeding or receiving iron infusions within 2 years prior to enrollment; ii. Significant skin involvement that could compromise daily activities or the ability to receive IV medications, or sclerodactyly that causes surface ulcerations, digital ulcerations, or ulcerating calcinosis lesions. e. History of receiving immunosuppressant therapy as follows: i. Excluded if receiving Mycophenolate mofetil within 30 days prior to enrollment, or Rituximab within 6 months prior to enrollment, or currently receiving Prednisone at a dose > 12 mg per day at time of enrollment; ii. Excluded if any immunosuppressant other than Mycophenolate mofetil, Rituximab or Prednisone, per above. e. Current pulmonary veno-occlusive disease (PVOD); f. Current pulmonary capillary hemangiomatosis (PCH); g. History of clinically significant patent foramen ovale (PFO) or other inter-atrial or inter-ventricular shunt; h. History of gastric antral vascular ectasia (GAVE), gastrointestinal or intracranial bleeding which, in the opinion of the investigator, will predispose subject to major bleeding events following Aria CV device placement and warfarin anticoagulation regimen; i. Active infection requiring antibiotic therapy within two (2) weeks of procedure; j. Blood dyscrasias that may, in the opinion of investigator(s), expose subject to unacceptable procedural risks such as severe or worsening leukopenia, anemia, thrombocytopenia, untreated iron deficiency or history of bleeding diathesis or coagulopathy. Anatomy is not suitable for placement of Aria CV device. Right heart valve regurgitation as follows: Moderate to severe (Grade 3 or 4) pulmonary valve regurgitation; Severe (Grade 4) tricuspid valve regurgitation. Hypersensitivity or contraindication to: Required medications (e.g., contrast agents, warfarin, heparin) which cannot be adequately managed; Materials in device including polyurethane, silicone, nickel, and titanium. Ineligible for or refuses blood transfusion. Pregnant, nursing or is planning to become pregnant in the next two years. Life expectancy of less than two years. Currently participating in or planning to participate in other investigational study that may interfere with the outcome of this study. For subject on supplemental oxygen therapy

•Subject adheres to the treatment regimen that in the opinion of the physician does not increase subject's safety. Previous diagnosis of cardiac amyloidosis. Unique Exclusion Criteria for WHO Group I: N/A Unique Exclusion Criteria for WHO Group II: Previous diagnosis of idiopathic hypertrophic subaortic stenosis (IHSS, also known as hypertrophic obstructive cardiomyopathy

•HOCM). Untreated severe aortic or mitral stenosis Diagnosis of heart failure with reduced ejection fraction (HFrEF) Previous diagnosis of nonobstructive hypertrophic cardiomyopathy. Unique Exclusion Criteria for WHO Group III: N/A

Conditions & Interventions

More Information

Description: The objective of this study is to evaluate the safety and feasibility of implantation of the Aria CV PH System in subjects with pulmonary hypertension (PH) and right heart dysfunction. In addition, the study will evaluate early signals of performance of the implanted system.
Study Contact: Gretchen Peichel - gpeichel@umn.edu
Principal Investigator: Thenappan Thenappan
Phase: N/A
IRB Number: STUDY00011174