

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

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: 18 years and over

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of Right heart dysfunction - symptomatic despite being on a stable drug regimen - 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 - ineligible for or refuses blood transfusion - pregnant, nursing or is planning to become pregnant in the next two years - see link to clinicaltrials.gov for complete inclusion and exclusion criteria

Exclusion Criteria:

- diagnosis of idiopathic hypertrophic subaortic stenosis - untreated severe aortic or mitral stenosis - heart failure with reduced ejection fraction

Conditions & Interventions

Interventions:

Device: Aria CV Pulmonary Hypertension System

Conditions:

Heart & Vascular

Keywords:

Pulmonary Hypertension, Right Heart Dysfunction

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.

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Phase: NA

IRB

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