Investigation of a Novel, magNetically levitated VAD for the treatment of refractOry left Ventricular heArT failurE (INNOVATE Trial)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- has received institutional approval for Left Ventricular Assist Device (LVAD) implantation - advanced heart failure refractory to advanced heart failure management or NYHA Class III with experience shortness of breath with mild physical activity - left ventricular ejection fraction (LVEF) ≤ 25% - women of childbearing age agree to use adequate contraception and have a negative pregnancy test - see link to clinicaltrials.gov for complete inclusion criteria

Exclusion Criteria:

- had cardiothoracic surgery within 30 days of implant - unable to have warfarin anticoagulation - history of organ transplantation - see link to clinicaltrials.gov for complete exclusion criteria

Conditions & Interventions

Interventions:
Device: BrioVAD System, Device: HeartMate 3
Conditions:
Heart & Vascular
Keywords:
Clinics and Surgery Center (CSC), Cardiovascular Diseases, CHF, Congestive Heart Failure, Heart Disease, LVAD

More Information

Description: The study is to evaluate the safety and effectiveness of the investigational BrioVAD® System compared to the commercially available HeartMate 3™ LVAS. Both the BrioVAD System and the HeartMate 3 LVAS are left ventricular assist devices (LVAD) that help pump blood from the lower left chamber of the heart to the rest of the body. An LVAD is used to treat weakened hearts or heart failure and may be a temporary measure while waiting for a heart transplant or a permanent solution.
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Phase: NA
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