Trial to Evaluate Safety And Effectiveness of Mechanical Circulatory Support in Patients With Advancing Heart Failure

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Subject has provided written informed consent by signing the study Informed Consent Form (ICF) prior to any clinical investigation-related procedure 2. LVEF ≤30% and Cardiac Index ≤ 2.5 L/min/m² 3. Limited functional status as demonstrated by 6MWT ≤ 350 m due to HF related reasons OR peak VO2 ≤ 14 mL/kg/min (or \<50% of predicted peak VO2 value) 4. NYHA Class IIIB or NYHA Class IV 5. Subject has ≥ 1 Heart Failure Hospitalization in the last 12 months 6. Subject is already implanted with a CardioMEMS PA Sensor OR willing to undergo a CardioMEMS PA Sensor implant 7. Subject is willing and able to be implanted with the HM3 LVAS if randomized to HM3 Group Randomization Criteria: 1. Subject has been implanted with a CardioMEMS PA Sensor for at least 90 days. 2. Subject is receiving guideline directed medical therapy with optimal doses (or documented medication contraindication or intolerance) of betablockers, Angiotensin-Converting-Enzyme-inhibitors or Angiotensin II Receptor Blockers or angiotensin receptor neprilysin inhibitor (if eligible), Mineralocorticoid Receptor Antagonists, Sodium-Glucose co-Transporter-2 (SGLT2) inhibitors, and diuretics for at least 30 of the last 90 days. 3. mean PAP ≥ 30 mmHg. 4. The subject will not be randomized if they have any other factor that represents inordinate risk for either continued GDMT or LVAD implant. Single Arm Registry Criteria: 1. Subject has received a CardioMEMS PA Sensor implant following enrollment in the trial. 2. Subject is receiving guideline directed medical therapy with optimal doses (or documented medication contraindication or intolerance) of betablockers, Angiotensin-Converting-Enzyme-inhibitors or Angiotensin II Receptor Blockers or angiotensin receptor neprilysin inhibitor (if eligible), Mineralocorticoid Receptor Antagonists, Sodium-Glucose co-Transporter-2 (SGLT2) inhibitors, and diuretics for at least 30 of the last 90 days. 3. mean PAP \<30 mmHg

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Exclusion Criteria:

1. Subject is \< 18 years of age at the time of informed consent. 2. Dependent on IV inotrope in the last 30 days. 3. Contra-indications to HM3 LVAS or CardioMEMS HF system. 4. Etiology of HF due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amyloidosis, or restrictive cardiomyopathy. 5. Technical obstacles to LVAD or CardioMEMS implantation which pose an inordinately high surgical risk, in the judgment of the implanter. 6. Existence of ongoing MCS. 7. Presence of mechanical aortic valve that will not be either converted to a bioprosthesis or oversewn at the time of LVAD implant. 8. History of any solid organ transplant. 9. Psychiatric disease/disorder, irreversible cognitive dysfunction or psychosocial issues that are likely to impair compliance with the study protocol and LVAS management. 10. Presence of an active, uncontrolled infection. 11. Complex congenital heart disease. 12. Currently Pregnant or capable of becoming Pregnant and Unwilling to Use Contraception with LVAD. 13. History of pulmonary embolism within 30 days prior to enrollment or history of recurrent (\>1 episode) pulmonary embolism and/or deep vein thrombosis. 14. Planned VAD or Bi-VAD support prior to enrollment. 15. Presence of any one of the following risk factors for or indications of severe end organ dysfunction or failure: 1. An INR ≥ 2.0 not due to anticoagulation therapy 2. An eGFR \< 30 mL/min/1.73 m2 and nonresponsive to diuretic therapy or receiving chronic dialysis. 3. Biopsy proven liver cirrhosis. 4. Need for chronic renal replacement therapy. 5. History of severe chronic obstructive pulmonary disease (COPD) defined by Forced Expiratory Volume FEV1 \< 30% predicted. 6. History of cerebrovascular disease with significant (\> 80%) uncorrected internal carotid stenosis. 7. Significant peripheral vascular disease (PVD) accompanied by ischemic rest pain or extremity ulceration. 16. Any condition other than HF that could limit survival to less than 24 months. 17. Participation in any other clinical investigation with an active treatment arm that is likely to confound study results or affect the study outcome.

Conditions & Interventions

Interventions:
DEVICE: CardioMEMS HF System, DEVICE: HeartMate 3 Left Ventricular Assist System, OTHER: Guideline Medical Directed Therapy
Conditions:
Heart Failure, Heart Diseases, Cardiovascular Diseases, Pulmonary Hypertension
Keywords:
Heart Failure, Left Ventricular Assist Device (LVAD), Guideline Directed Medical Therapy (GDMT), Non-inotrope Dependent, Pulmonary Artery Pressure, Hemodynamic Monitoring, Medical Management, CardioMEMS, HeartMate 3 (HM3), Ambulatory Advanced Heart Failure

More Information

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