

Feasibility of the SCD in Cardiorenal Syndrome Patients Awaiting LVAD

NCT03836482

Status	RECRUITING
Phase	Not Applicable
Sponsor	SeaStar Medical
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (22)

- Age of 18 years and older.
- Evidence of systemic inflammation: blood CRP \geq 4.5 mg/L or IL-6 \geq 5.0 pg/ml or neutrophil to lymphocyte ratio \geq 3.0.
- Primary hospitalization for acute decompensated chronic systolic heart failure.
- Potential LVAD candidate with:
 - a) Left ventricular ejection fraction \geq 25% (for potential destination therapy) or \geq 35% (for potential bridge to transplantation) as confirmed by baseline imaging procedure b) NYHA class IIIb or IV chronic (\geq 90 days) systolic heart failure, with failure to respond to optimal medical therapy (beta blocker, ACE inhibitor or ARB or valsartan/sacubitril, aldosterone antagonist, SGLT2i, unless not tolerated or contraindicated, and loop diuretic, as needed) for 45 of the last 60 days c) Known previous peak exercise oxygen consumption $<$ 14 mL/Kg/min or if unable to exercise, dependent on an intra-aortic balloon pump, short-term mechanical circulatory support device or intravenous inotropes unless inotropes contraindicated for clinical reasons (e.g., ventricular arrhythmias)

... and 17 more (see full listing online)

Exclusion (16)

- Any clear contraindication to LVAD therapy that is unlikely to resolve with improvement in renal function and volume status
- Prior sensitivity to dialysis device components
- Active bacteremia
- Temperature \geq 101.5 F or WBC \geq 10,000 K/uL or any patient with suspected systemic infection.
- Metastatic malignancy requiring palliative chemo, biologic, or radiation

... and 11 more (see full listing online)

Locations (1 total)

University of Michigan, Ann Arbor, Michigan, United States