Diuretics Alone vs. Aortix Endovascular Device for Acute Heart Failure

Status: RECRUITING

Eligibility Criteria

Age: 21 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria (Randomized Study): * Currently admitted to the hospital with a primary diagnosis of decompensated heart failure, irrespective of ejection fraction (EF); * Patients should be on maximally tolerated diuretic therapy and not diuresing sufficiently before being enrolled in DRAIN-HF. After being up-titrated on diuretics, patients should be followed for at least 24 hours on the higher of: i) furosemide 80 mg IV bid or equivalent or ii) IV furosemide or equivalent IV loop diuretic at a dose 2.5 x total daily home dose of furosemide equivalents in 2 divided doses, as tolerated, patient must have: Urine Output \<1,500mL in a 12-hour period OR a Net Fluid Loss ≤375mL in a 12-hour period. * Persistent signs and/or symptoms of congestion as evidenced by at least 2+ pitting edema, elevated jugular venous pressure \>12 cm water or ascites after treatment with IV diuretics per inclusion criterion 2.; * Age \>21 years and able to provide written informed consent; * Negative pregnancy test if patient is of child-bearing potential. Exclusion Criteria (Randomized Study): * Treatment with high dose IV inotropes within the last 48 hours prior to enrollment. High dose is defined as \>5 µg/kg/min dopamine OR \>5 µg/kg/min dobutamine OR \>0.375 µg/kg/min milrinone; * Active and ongoing hypotension with a systolic blood pressure \<90 mmHg lasting more than 30 minutes or a mean arterial pressure (MAP) \<60 mmHg lasting more than 30 minutes at enrollment; * Treatment with vasopressors (defined as phenylephrine, norepinephrine, epinephrine or, vasopressin) within 48 hours prior to enrollment; * An estimated PASP of \>80 mmHg as measured on echocardiogram or echocardiographic evidence of primarily right heart failure; * Treatment with IV diuretics (does not have to be continuous) for ≥21 days during the current hospitalization (including time spent at an outside hospital); * Acute kidney failure defined as an increase in serum creatinine to ≥4.0mg/dL (≥353.6 µmol/L) at enrollment; * Evidence of contrast induced nephropathy, nephritis or nephrotic syndrome; * Prior kidney transplant, single kidney, partial nephrectomy OR use of dialysis, continuous renal replacement therapy (CRRT) or ultrafiltration in the last 90 days prior to enrollment; * Confirmed decompensated cirrhosis (defined as Child Pugh class B or C) or concern for shock liver (AST \> 1000U/L or total Bilirubin \> 5.0mg/dl) at enrollment; * Presence of an active, uncontrolled infection that would preclude safe placement or removal of the device; * Prior heart transplant or likely heart transplantation before the 30- day follow-up visit; * Current or previous support with a durable LVAD at any time or planned LVAD insertion before the 30-day follow-up visit; * Use of an intra-aortic balloon pump (IABP), extracorporeal membrane oxygenation (ECMO), or percutaneous ventricular assist devices (e.g. Impella or TandemHeart) within the last 30 days; * Known amyloidosis of any type; * Acute myocardial infarction Type 1 within 30 days of enrollment, or planned coronary revascularization in the next 30 days; * Stroke within 30 days of enrollment; * Severe Bleeding Risk (any of the following): 1. Previous intracranial bleed unless there is documentation in the medical record (from a physician that is not part of the study) that the patient can safely use anticoagulation for 7 days, 2. GI bleeding within 6 months requiring hospitalization and/or transfusion, 3. Recent major surgery within 30 days if the surgical wound is judged to be associated with an increased risk of bleeding, 4. Procedure with arterial ilio-femoral access \> 6 FR within 30 days, 5. Platelet count \<75,000 cells/mm3, 6. Uncorrectable bleeding diathesis or coagulopathy (e.g. INR ≥2 not due to anticoagulation therapy) or hypercoaguable state including HIT; 7. Inability to tolerate anticoagulation therapy for up to 7 days. * Contraindicated Anatomy : 1. Descending aortic anatomy that would prevent safe placement of the device \[\<18 mm or \>31 mm aorta diameter at deployment location (measured between the superior aspect of the T10 vertebra and superior aspect of the L1 vertebra)\], 2. Ilio-femoral diameter or peripheral vascular anatomy that would preclude safe placement of a 21F (outer diameter) introducer sheath, 3. Femoral artery depth inconsistent with use of closure device, 4. Abnormalities or severe vascular disease that would preclude safe access and device delivery (e.g. aneurysm with thrombus, marked tortuosity, significant narrowing or inadequate size of the abdominal aorta, iliac or femoral arteries, or severe calcification), 5. Known connective tissue disorder (e.g. Marfan Syndrome) or other aortopathy at risk of vascular injury, 6. Any endovascular stent graft in the descending aorta. Any endovascular stent graft in the femoro-iliac vessels that is not well endothelialized and would preclude safe introduction/removal of the Aortix pump as demonstrated by imaging. * Known hypersensitivity or contraindication to study or procedure medications (e.g. anticoagulation therapy) or device materials (e.g. history of severe reaction to nickel or nitinol); * Participation in any other clinical investigation that is likely to confound study results or affect the study; * Poor health such that the patient is unable to undergo the Aortix device placement/retrieval and/or unlikely to be able to survive to the 30-day visit; * Unable or unwilling to undergo screening (imaging, PA Catheter placement), device implant and retrieval procedures or return for 30-day visit. Inclusion Criteria (Advanced Heart Failure Registry): * Currently admitted to the hospital with a primary diagnosis of decompensated HF, irrespective of ejection fraction (EF). * Patient has already been evaluated and indicated to receive an LVAD or heart transplant and will receive the LVAD or be listed for heart transplantation in the next 30 days if their congestion status and renal function improves. * Patient must have been treated with ≥ 80 mg IV furosemide bid or equivalent and have evidence of increasing diuretic dosing requirements over the past 12 months, as tolerated. * Must have evidence of refractoriness to medical management as documented by persistent signs and/or symptoms of congestion as evidenced by at least 2+ pitting edema, elevated jugular venous pressure \>12 cm water, or ascites after treatment with IV diuretics for a minimum of 24 hours. * Serum creatinine ≥ 2.0 mg/dL AND eGFR ≤ 45 ml/min/1.73m2 at time of enrollment * Age ≥ 21 years and able to provide written informed consent. * Negative pregnancy test if patient is of childbearing potential. Exclusion Criteria (Advanced Heart Failure Registry): * Treatment with high dose IV inotropes within 48 hours prior to enrollment. High dose is defined as any one of the following: \>5 µg/kg/min dopamine OR \>5 µg/kg/min dobutamine OR \>0.375 µg/kg/min milrinone. * Active and ongoing hypotension with a systolic blood pressure \<80 mmHg lasting more than 30 minutes or a mean arterial pressure (MAP) \<55 mmHg lasting more than 30 minutes at enrollment. * Treatment with vasopressors (defined as phenylephrine, norepinephrine, epinephrine or, vasopressin) within 48 hours prior to enrollment. * An estimated PASP of \>80 mmHg as measured on echocardiogram or echocardiographic evidence of primarily right heart failure. * Acute kidney failure defined as an increase in serum creatinine to ≥ 4.0mg/dL at enrollment. * Evidence of contrast-induced nephropathy, nephritis, or nephrotic syndrome. * Prior kidney transplant, single kidney, partial nephrectomy OR use of dialysis, continuous renal replacement therapy (CRRT), or ultrafiltration in the last 90 days prior to enrollment. * Confirmed decompensated cirrhosis (defined as Child Pugh class B or C) or concern for shock liver (AST \> 1000U/L or total Bilirubin \> 5.0mg/dl) at enrollment. * Presence of an active, uncontrolled infection that would preclude safe placement or removal of the device. * Current or previous support with a durable LVAD. * INTERMACS Profile 1 at enrollment. * Currently on mechanical ventilatory support. * Use of an intra-aortic balloon pump (IABP) within the last 14 days or use of an extracorporeal membrane oxygenation (ECMO) or percutaneous ventricular assist device (e.g., Impella or TandemHeart) within the last 30 days. * Known amyloidosis of any type. * Acute myocardial infarction Type 1 within 30 days of enrollment or planned coronary revascularization in the next 30 days. * Stroke within 30 days of enrollment. * Severe Bleeding Risk (any of the following): * Previous intracranial bleed unless there is documentation in the medical record (from a physician that is not part of the study) that the patient can safely use anticoagulation for 7 days. * GI bleeding within 6 months requiring hospitalization and/or transfusion. * Recent major surgery within 30 days if the surgical wound is judged to be associated with an increased risk of bleeding. * Procedure with arterial ilio-femoral access \> 6 Fr within 30 days. * Platelet count \<75,000 cells/mm3 . * Uncorrectable bleeding diathesis or coagulopathy (e.g., INR≥ 2 not due to anticoagulation therapy) or hypercoagulable state including HIT. * Inability to tolerate anticoagulation therapy for up to 7 days. * Contraindicated Anatomy : * Descending aortic anatomy that would prevent safe placement of the device \[\<18 mm or \>31 mm aorta diameter at deployment location (measured between the superior aspect of the T10 vertebra and superior aspect of the L1 vertebra)\]. * Ilio-femoral diameter or peripheral vascular anatomy that would preclude safe placement of a 21 Fr (outer diameter) introducer sheath. * Femoral artery depth inconsistent with use of closure device. * Abnormalities or severe vascular disease that would preclude safe access and device delivery (e.g., aneurysm with thrombus; marked tortuosity; significant narrowing or inadequate size of the abdominal aorta, iliac, or femoral arteries; or severe calcification). * Known connective tissue disorder (e.g., Marfan Syndrome) or other aortopathy at risk of vascular injury. * Any endovascular stent graft in the descending aorta. Any endovascular stent graft in the femoro-iliac vessels that is not well endothelialized and would preclude safe introduction/removal of the Aortix pump as demonstrated by imaging. * Known hypersensitivity or contraindication to study or procedure medications (e.g., anticoagulation therapy) or device materials (e.g., history of severe reaction to nickel or nitinol). * Participation in any other clinical investigation that is likely to confound study results or affect the study. * Poor health such that the patient is unable to undergo the Aortix device placement/retrieval and/or unlikely to be able to survive to the

study results or affect the study. * Poor health such that the patient is unable to undergo the Aortix device placement/retrieval and/or unlikely to be able to survive to the 30-day visit. * Unable or unwilling to undergo screening, device implant and retrieval procedures, or return for 30-day visit.

Conditions & Interventions

Interventions:
DEVICE: Aortix System
Conditions:
Heart Failure, Cardiorenal Syndrome, Cardio-Renal Syndrome, ADHF, Heart Failure, Systolic, Heart Failure, Diastolic, Heart Failure, With Decompensation, Heart Failure, Congestive
Keywords:
mechanical circulatory support, percutaneous

More Information

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