Fluid Management of Acute Decompensated Heart Failure Subjects Treated With Reprieve System (FASTR-II) (IDE-G210258)

Status: RECRUITING

Eligibility Criteria

Age: 22 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Diagnosis of HF with expected hospitalization \>24 hours, with \>1 new or worsening symptom and \>2 physical examination, laboratory, or invasive findings of HF, and receiving or with plans to receive a HF-specific treatment 2. ≥10 lb. (4.5 kg) above dry weight as estimated by health care provider. 3. Current outpatient prescription for daily loop diuretic. 4. Participants ≥ 22 years of age able to provide informed consent and comply with study procedures. 5. Elevated risk of diuretic resistance, as indicated by at least one of the following: Baseline hypochloremia OR Urine output \<1L in the 6 hours following IV loop diuretic \>=40 mg furosemide equivalent OR Spot urine sodium \<100 mmol/L 1-2 hours after IV loop diuretic \>= 40 mg furosemide equivalent

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Exclusion Criteria:

1. Urologic issues that would predispose the participant to a high rate of urogenital trauma or infection with catheter placement or known inability to place a Foley catheter. 2. Hemodynamic instability as defined by any of the following: sustained systolic blood pressure \<90 mmHg for \>15 minutes within the past 48 hours, use of IV vasopressors or inotropes within past 48 hours, and/or current or previous mechanical circulatory support within the last week. 3. Uncontrolled arrhythmias defined as sustained HR \>130 beats/min for \>10 minutes within the past 48 hours. 4. Severe lung disease with chronic home oxygen requirement \>2L/min. 5. Acute infection with evidence of systemic involvement (e.g., clinically suspected infection with fever or elevated serum white blood cell count). 6. Estimated glomerular filtration rate (eGFR) \<25 ml/min/1.73m2 (calculated with either MDRD or CKD-EPI) or current use of renal replacement therapy (RRT). 7. Significant left ventricular outflow obstruction, severe uncorrected complex congenital heart disease, known severe stenotic valvular disease, severe infiltrative or constrictive cardiomyopathy or other diagnosis that would make aggressive decongestion unsafe. 8. Current or recent (\< 30 days) type I myocardial infarction (e.g., acute coronary syndrome such as NSTEMI or STEMI from plaque rupture), coronary artery bypass surgery, or stroke. An isolated troponin elevation (e.g., from volume overload or demand ischemia) is not a reason for exclusion. 9. Severe electrolyte abnormalities (e.g., serum potassium \<3.0 mEq/L, magnesium \<1.3 mEq/L or sodium \<125 mEq/L). Note: These are based on baseline/screening labs. Participants whose electrolyte levels are repleted cannot be reassessed for inclusion in the trial. 10. Other concomitant disease or condition the investigator believes will make it difficult to follow instructions or comply with study procedures and/or follow-up visits, including expected prolonged hospitalization for reasons other than decongestive therapy 11. Currently enrolled in an interventional trial (observational studies are permitted). 12. Life expectancy less than 6 months. 13. Women who are pregnant or breastfeeding.

Conditions & Interventions

Interventions:
DEVICE: Reprieve System, DRUG: furosemide infusion
Conditions:
Acute Decompensated Heart Failure

More Information

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