Endovascular Ablation of the Right Greater Splanchnic Nerve in Subjects Having HFpEF (Rebalance-HF)

Status: OPEN TO ACCRUAL

Eligibility Criteria

Age: 40 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Subjects ? 40 years of age 2. Chronic heart failure defined as at least one of the following: 1. Symptoms of HF requiring current treatment with diuretics (intermittent or continuous) for > 30 days, AND 2. NYHA class II with a history of > NYHA class II in the past year, NYHA class III, or ambulatory NYHA class IV symptoms (paroxysmal nocturnal dyspnea, orthopnea, dyspnea on mild or moderate exertion) at screening; or signs of HF (any rales post cough, chest x-ray demonstrating pulmonary congestion), AND 3. > 1 HF hospital admission (with HF as the primary, or secondary diagnosis);

• OR

•treatment with intravenous (IV) diuretics, or intensification of oral diuresis for HF in a healthcare facility within the 12 months prior to study entry;

• OR

•NT-pro BNP value > 150 pg/ml in normal sinus rhythm, > 450 pg/ml in atrial fibrillation within the past 6 months;

• OR

•BNP value > 50 pg/ml in normal sinus rhythm, > 150 pg/ml in atrial fibrillation within the past 6 months. 3. Ongoing stable GDMT HF management (unless unable to tolerate GDMT) and management of potential comorbidities according to the 2017 ACCF/AHA Guideline for the Management of Heart Failure, with no significant changes [>100% increase or 50% decrease] for a minimum of 1 month prior to screening, that is expected to be maintained without change for at least 3 months. 4. LVEF ? 50 % (site determined by TTE) in the past 3 months. 5. Site determined elevated PCWP documented by right heart catheterization by PCWP ? 25 mmHg during supine ergometer exercise a. PCWP to be evaluated by a Swan Ganz procedure performed either prior to the day of the index procedure or on the day of the index procedure 6. Subject is willing and able to provide appropriate study-specific informed consent, follow protocol procedures, and comply with follow-up visit requirements.

Exclusion Criteria:

1. MI (type I) and/or percutaneous cardiac intervention within past 3 months; CABG in past 3 months, or current indication for coronary revascularization. 2. Cardiac Resynchronization Therapy initiated within the past 3 months prior to screening. 3. Advanced heart failure defined as one or more of the below: 1. ACC/AHA/ESC Stage D heart failure, non-ambulatory NYHA Class IV HF 2. Cardiac index < 2.0 L/min/m2 3. Inotropic infusion (continuous or intermittent) for LV EF< 30% within the past 6 months prior to screening 4. Subject is on the cardiac transplant waiting list 4. BMI > 45 kg/m2 5. Inability to perform 6-minute walk test (distance < 100 meters), OR ability to perform 6-minute walk test distance > 450 meters. 6. Admission for HF within the 30 days prior to planned index procedure. 7. In the last 3 years an ejection fraction (EF) below 40 8. Systolic BP < 100 mmHg or > 170 mmHg despite appropriate medical management. 9. Symptomatic orthostatic hypotension or orthostatic hypotension requiring treatment (orthostatic hypotension is defined as systolic blood pressure decrease of >20mmHg and/or increase in heart rate >20 bpm upon going from supine to standing position). 10. Arterial oxygen saturation < 90 % on room air. 11. Presence of significant valve disease defined by the site cardiologist as: 1. Mitral valve stenosis defined as <1.5 cm2 (or greater than mild) 2. Mitral valve regurgitation defined as grade > 3+ MR 3. Tricuspid valve regurgitation defined as grade > 3+ TR 4. Aortic valve disease defined as > 3+ AR or > severe AS 12. Hypertrophic cardiomyopathy, restrictive cardiomyopathy, constrictive pericarditis, cardiac amyloidosis, or other infiltrative cardiomyopathy (e.g., hemochromatosis, sarcoidosis) 13. Vessel tortuosity or variant vascular anatomy that could preclude the access or maneuvering of the interventional device from the access site to target vessel. This includes previous spine surgery that may impact the ability to access and treat the target sites of T11 and T10. 14. Mean resting right atrial pressure (RAP) > 20 mmHg based upon screening right heart catheterization. 15. History of severe liver cirrhosis 16. Dialysis dependent; or estimated-GFR <25 ml/min/1.73 m2 by MDRD equation. 17. Baseline status of persistent atrial fibrillation with resting HR >100 beats per minute that could obfuscate RHC interpretation. 18. Chronic pulmonary disease requiring continuous home oxygen OR hospitalization for exacerbation (including intubations) in the 12 months before study entry OR known history of GOLD Class II or higher COPD. 19. Currently participating in conflicting investigational drug or device study. 20. Life expectancy <12 months for non-cardiovascular reasons. 21. Any condition, or history of illness or surgery that, in the opinion of the Investigator, might confound the results of the study or pose additional risks to the patient. 22. Females who are not pregnant or lactating and not or planning to become pregnant for the duration of the study during the next year.

Conditions & Interventions

Interventions:
Device: Satera GSN Ablation, Device: Sham Control
Conditions:
Heart Failure With Preserved Ejection Fraction, Diseases of Circulatory System (390-459)

More Information

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Phase: N/A
IRB Number: HM20022228
System ID: NCT04592445
