Left vs Left Randomized Clinical Trial

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Men and women 18 years of age or older. * A LVEF ≤ 50% within 6 months prior to enrollment. * Resting QRS duration ≥130 ms as evidenced by a historical 12-lead ECG prior to enrollment OR anticipated right ventricular pacing \>40% OR device in place with right ventricular pacing \> 40%. * Are optimized on HF guideline directed medical therapy according to current HF published guidelines OR patient's physician will make an effort to start all guideline-directed medical therapy and titrate doses up as permitted by the participant clinical status and co-morbidities prior to implantation procedure.

Exclusion Criteria:

* Women who are pregnant, lactating, or plan to become pregnant during the course of the trial. * Participants with angiographic evidence of coronary disease who are candidates for coronary revascularization and are likely to undergo coronary artery bypass graft surgery or percutaneous coronary, intervention in the next three (3) months. * Enzyme-positive myocardial infarction within the past three (3) months prior to enrollment. * Coronary artery bypass graft surgery or percutaneous coronary intervention (balloon and/or stent angioplasty) within the past three (3) months prior to enrollment. * Reversible non-ischemic cardiomyopathy (e.g., acute viral myocarditis). * Participants with Chagas disease, cardiac sarcoidosis or amyloidosis. * Expected to receive left ventricular assist device or heart transplantation within 6 months. * Participants with primary severe valvular disease (e.g., aortic stenosis). * Have a life expectancy of less than 12 months. * Participants with irreversible brain damage from preexisting cerebral disease. * Participants with a contrast dye allergy unable or unwilling to undergo pretreatment with steroids and/or diphenhydramine. * Participants participating in any other interventional cardiovascular clinical trial. * Participants who would be unable to comply with the study's follow-up visit schedule; or * Participants who had any prior unsuccessful attempt at implantation of biventricular pacing (BiVP), His Bundle Pacing (HBP), or Left Bundle Branch Pacing (LBBP) device.

Conditions & Interventions

Interventions:
DEVICE: His/LBBP, DEVICE: BiVP
Conditions:
Heart Failure, Heart Failure With Reduced Ejection Fraction, AV Block, LBBB, RBBB, Intraventricular Conduction Delay, Pacing-Induced Cardiomyopathy

More Information

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Phase: NA
IRB
Number:
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