Cardiac Resynchronization Therapy in Previously Untreatable and High Risk Upgrade Patients

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is also accepting healthy

Healthy Volunteers: volunteers

Inclusion/Exclusion: Inclusion Criteria 1. Patient with a class I or IIa (1) or (2) indication for implantation of a CRT-D device according to current available guidelines (with additional QRS criteria on Class IIa (1)): 1. Class I: NYHA II, III, IV, EF ≤ 35%, LBBB, QRS ≥ 150ms 2. Class IIa (1): NYHA II, III, IV, EF≤ 35%, LBBB, QRS ≥ 130 to < 150ms 3. Class IIa (2): NYHA II, III, IV, EF≤ 35%, non-LBBB, QRS ≥ 150ms 2. Patient is a: 1. 'Non-responder' [Not Enrolling]: Patients who have a CRT system that is functional and despite an adequate trial of Guideline Directed Medical Therapy (GDMT) and attempts at optimal device programming the patient has not responded to therapy for a minimum of 6 months. Non-response is defined as:

• EF has remained unchanged or worsened (defined as < 5% increase since implant), and

• The patient's clinical status based in the totality of available clinical evidence (such as NYHA Class, exercise tolerance, QOL, or global assessment) has remained unchanged or worsened, as determined by the local Site Enrollment Committee OR 2. 'Previously Untreatable': Patients who have a full or partial CRT system, who meet general inclusion criteria and are deemed as 'previously untreatable' for one of the following reasons: i. Patients in whom CS lead implantation for CRT has failed

• CS lead implant was attempted but abandoned due any of the following: difficult CS access or anatomy, inadequate lead location, inadequate pacing thresholds, persistent phrenic nerve pacing, or other procedural challenges ii. CS lead implanted but has been programmed OFF

• LV lead that was implanted but not operational includes patients in whom the LV lead is inoperative or programmed off due to improper function such as high threshold, non-capture, phrenic nerve pacing, lead failure, lead dislodgement, or sub-optimal LV lead location OR c. 'High Risk Upgrade: Patients who have a relative contraindication to CS lead implant, due to:

• venous occlusion or lesion precluding implant

• pocket infection risk (at co-implanted device site)

• considered high risk for CS implant due to co-morbidities 3. Patients on a stable Guideline Directed Medical Therapy (GDMT) 4. Patient must be 18 years old or over 5. Patient has signed and dated informed consent 6. Patient has suitable anatomy for implant of the WiSE CRT System (e.g. adequate acoustic window, LV wall thickness in target implant area ≥ 5 mm, absence of LV wall structural abnormalities which may preclude implant) Exclusion Criteria Patients who meet any one of these criteria will be excluded from the investigation: 1. Pure RBBB 2. LVEDD ≥ 8cm 3. Non-ambulatory or unstable NYHA class IV 4. Contraindication to heparin, chronic anticoagulants or antiplatelet agents 5. Triple anticoagulant patients who cannot tolerate peri-procedural stopping of anticoagulation therapy 6. Attempted device implant (pacemaker, ICD, CRT, LV lead) or successful co-implant within prior 30 days. 7. Patients with planned or expected lithotripsy treatment post implant 8. Life expectancy of < 12 months 9. Chronic hemodialysis 10. Stage 4 or 5 renal dysfunction defined as eGFR < 30 11. Grade 4 mitral valve regurgitation 12. Noncardiac implanted electrical stimulation therapy devices 13. Patients with a prosthetic aortic valve in which the electrode cannot be implanted via a transseptal approach 14. Patients with a prosthetic mitral valve in which the electrode cannot be implanted via a retrograde aortic approach 15. Unstable angina, acute MI, CABG, or PTCA within the past 1 month 16. Correctable valvular disease that is the primary cause of heart failure 17. Recent CVA or TIA (within the previous 3 months) 18. Patients with a history of paroxysmal or persistent atrial fibrillation/flutter are excluded if they have had a documented AF episode > 30 min or a cardioversion in the past 1 month. 19. Patients with permanent AF are excluded if they have intact AV node conduction (RV pacing <95%) 20. Already included in another clinical study that could confound the results of this study 21. Pregnancy 22. Known drug or alcohol addiction or abuse 23. Moderate or severe aortic stenosis 24. Subject unable to attend follow-up at the investigative center or unable, for physical or mental reasons, or to comply with the trial's procedures 25. For Part II Randomized patients only, those who will not tolerate being randomized to the Control Group for 6 months

Conditions & Interventions

Interventions:
Device: WiSE System
Conditions:
Heart Failure

More Information

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Phase: N/A
IRB Number: HM20014794
System ID: NCT02922036