Cardiac Resynchronization Therapy Delivery Guided Non-Invasive Electrical and Venous Anatomy Assessment

Status: Recruiting

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Eligible subjects shall meet all following criteria:

• Appropriately signed and dated informed consent.

• Age ≥18 years at time of consent.

• CRT indication according to the 2021 ESC guidelines on cardiac pacing and CRT (class I and IIA indication in patients with LBBB QRS morphology) or to 2017 AHA/ACC/HFSA guidelines (COR I).

• Sinus rhythm

• QRS duration ≥130 ms

• Left bundle branch block

• Left ventricular ejection fraction ≤35%

• Symptomatic heart failure NYHA class ≥ II

• Documented stable medical treatment for at least 6 months

• No cardiovascular intervention during the last 6 month Exclusion Criteria are:

• History of persistent or permanent atrial fibrillation

• Previous pacemaker or ICD implantation

• Indication to pacing due to bradycardia

• Patients considered for His bundle pacing or cardiac conduction pacing

• Patients with unstable angina

• Subject experienced a recent myocardial infarction, within 40 days prior to enrollment

• Subject underwent coronary artery bypass graft or valve surgery, within 90 days prior to enrollment

• Subject is post heart transplantation, or is actively listed on the transplantation list, or has reasonable probability (per investigator's discretion) of undergoing transplantation in the next year

• Subject is implanted with a left ventricular assist device

• Subject is on continuous or uninterrupted infusion (inotropic) therapy for heart failure

• Subject has severe aortic stenosis (with a valve area of <1.0 cm2 or significant valve disease expected to be operated within study period)

• Subject has congenital heart disease

• Subject has a mechanical right-sided heart valve

• Subject has a life expectancy of less than one year in the opinion of the investigator

• Pregnant or breastfeeding women, or women of child bearing potential and who are not on a reliable form of birth control

• Subject is enrolled in one or more concurrent studies that would confound the results of this study

• Patients who have contraindications to CT scanning.

• Patients with chronic kidney diseases and estimated glomerular filtration rate (eGMR) calculated based on CKD-EPI 2009 < 40 ml/min/1.73m2

Conditions & Interventions

Interventions:
Device: CRT implantation guided by XSpline, a non-invasive electrical and venous anatomy assessment
Conditions:
Cardiac Resynchronization Therapy, Chronic Heart Failure, Left Bundle-Branch Block
Keywords:
Non-invasive activation mapping, Coronary Sinus

More Information

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