BeAT-HF

NCT02627196

Principal Investigator: Dr. Peter Fattal, MD (Covenant)

Condition: Heart Failure

Device: BAROSTIM NEO® System

Official Title: Barostim Neo® - Baroreflex Activation Therapy® for Heart Failure

Sponsor: CVRx, Inc.

Purpose: The purpose of this trial is to develop valid scientific evidence for safety and effectiveness of Baroreflex Activation Therapy® with the BAROSTIM NEO® System in subjects with heart failure, defined as New York Heart Association (NYHA) functional class III and left ventricular ejection fraction (LVEF) ≤ 35% despite being treated with the appropriate heart failure guideline directed therapy, excluding subjects eligible for or actively receiving Cardiac Resynchronization Therapy (CRT).

Inclusion Criteria:

1. Currently NYHA Class II or III heart failure.
2. Left ventricular ejection fraction ≤ 35% within 45 days prior to randomization.
3. Heart failure accompanied by a BNP ≥ 100 or NT-proBNP ≥ 400 within 45 days prior to randomization, or a heart failure hospitalization in the past 12 months
4. On optimal, stable, Guideline Directed Medical Therapy (GDMT) per country specific guidelines for the treatment of heart-failure throughout screening/baseline evaluation and for at least 4 weeks prior to obtaining any post-consent screening parameters.
5. Six-minute hall walk (6MHW) ≥ 150m AND ≤ 400m within 45 days prior to randomization.
6. The artery planned for the BAROSTIM implant must have:
   - At least one carotid bifurcation as identification by a bilateral carotid duplex ultrasound within 6 months prior to randomization that is:
     - Below the level of the mandible
     - Has no ulcerative carotid arterial plaques
     - Has no carotid atherosclerosis producing at 50% or greater reduction in linear diameter of the internal carotid
     - Has no carotid atherosclerosis producing at 50% or greater reduction in linear diameter of the distal common carotid
   - No prior surgery, radiation, or endovascular stent placement in the carotid artery or the carotid sinus region.
7. If female and of childbearing potential, must use a medically accepted method of birth control and have a negative pregnancy test within 14 days of randomization.
8. Received a standard cardiac work up and is an appropriate candidate for the study and the surgical procedure as determine by a trial cardiologist and trial surgeon.
9. Subjects implanted with a cardiac rhythm management device that does not utilize an intracardiac lead, or implanted with a neurostimulation device, must be approved prior to enrollment.
10. Signed a CVRx-approved informed consent form for participation in this trial.

Exclusion Criteria:

1. Received cardiac resynchronization therapy (CRT) within 6 months of randomization, or is actively receiving CRT.
2. Currently have a Class I indication for a cardiac resynchronization therapy (CRT) device according to the American Heart Association/American College of Cardiology/European Society of Cardiology (AHA/ACC/ESC) guidelines for the treatment of congestive heart failure.
3. Known or suspected baroreflex failure or autonomic neuropathy.

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Exclusion Criteria (Continued):

4. AHA/ACC Stage D heart failure within 45 days prior to randomization.
5. BMI > 40.
6. Serum estimated glomerular filtration rate (eGFR) < 25 mL/min/173m^2 within 45 days prior to randomization.
7. Recurring resting heart rate of either < 60 beats per minute(bpm) or > 100 bpm via clinic measurements within 45 days prior to randomization. (Heart rate of < 60bpm is not applicable to subjects with an implanted device capable of pacing).
8. Recurring symptomatic hypotension within 45 days prior to randomization.
9. Significant uncontrolled symptomatic bradyarrhythmias or unstable ventricular arrhythmias.
10. Subjects with any surgery that has occurred, or is planned to occur, within 45 days of the BAROSTIM NEO® implant procedure.
11. Episode of NYHA class IV heart failure with acute pulmonary edema within 45 days prior to randomization.
12. Any of the following within 3 months of randomization:
    - Myocardial infarction
    - Unstable angina
    - Percutaneous coronary intervention
    - Cerebral vascular accident or transient ischemic attack
    - Sudden cardiac death
13. Solid organ or hematologic transplant, or currently being actively evaluated for an organ transplant.
14. Has received or is receiving left ventricular assist device (LVAD) therapy.
15. Has received or is receiving chronic dialysis.
16. Heart failure secondary to a reversible cause, such as cardiac structural valvular disease, acute myocarditis and pericardial constriction.
17. Primary pulmonary hypertension.
18. Infiltrative cardiomyopathy.
19. Severe chronic obstructive pulmonary disease (COPD) or severe restrictive lung disease.
20. Active malignancy.
21. Current or planned treatment with intravenous positive inotrope therapy
22. Life expectancy less than one year.
23. Clinically significant psychological condition that, in the physician's opinion, would prohibit the subject's ability to meet the protocol requirements.
24. Unable or unwilling to fulfill the protocol medication compliance, testing, and follow-up requirements.
25. Enrolled and active in another clinical trial (unless previously approved by the CVRx Clinical Department).
26. Subjects with known allergies to silicone and titanium

Source: https://clinicaltrials.gov/ct2/show/NCT02627196
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