Barostim-Enabled NEurohormonal Intervention For Improving Treatment of Heart Failure

NCT07232030

Status	RECRUITING
Phase	Not Applicable
Sponsor	CVRx, Inc.
Enrollment	2,500 participants

Key Eligibility Criteria

Inclusion (16)

- Age 18 years or above
- NYHA Functional Class II or III heart failure symptoms at the time of screening
- Left ventricular ejection fraction \< 50% within 6 months of consent
- Heart failure accompanied by either:
- Screening local lab NT-proBNP e 400 AND \< 5,000 pg/mL or a BNP e100 AND \< 1,250 pg/mL, adjusted for BMI in a stable outpatient setting OR

... and 11 more (see full listing online)

Exclusion (29)

- Any contraindications to Barostim as noted in Instructions for Use.
- An existing device which contraindicates Barostim specifically or unipolar therapy in general.
- Advanced heart failure defined by any of the following:
- AHA/ACC Stage D heart failure.
- Two or more NT-proBNP results \>5,000 pg/mL or BNP \>1,250 pg/mL in a stable outpatient setting within 3 months prior to consent. If participant is taking sacubitril/valsartan (i.e. Entresto®), NT-proBNP must be used for screening eligibility.

... and 24 more (see full listing online)

Locations (1 total)

BayCare Health Systems, Tampa, Florida, United States