Trial Description

Title

Barostim Therapy™ in Heart Failure with Preserved Ejection Fraction (HFrEF): A Data Collection Registry with the CE-Marked Barostim neo™ System

Trial Acronym

HFrEF Registry

URL of the trial

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Brief Summary in Lay Language

This registry is a collection of data in patients with an already implanted Barostim Therapy neo device for the treatment of hypertension and concomitant heart failure. The device itself is already approved for the treatment. At the following times data about the treatment are collected: before the device was implanted, and after 3, 6 and 12 months after the device was turned on.

Brief Summary in Scientific Language

The purpose of this registry is to measure the effect of Barostim Therapy with the Barostim Neo system in the commercial setting in subjects implanted under the CE Marked indication for heart failure with reduced ejection fraction (HFrEF).

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00009443**
- Date of Registration in DRKS: **2015/10/05**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **Nr. 6956 , Ethikkommission der Medizinischen Hochschule Hannover**

Secondary IDs

- Sponsor-ID: **360049 ((CVRx Incorporated))**

Health condition or Problem studied

- ICD10: **I50.9 - Heart failure, unspecified**

Interventions/Observational Groups

- Arm 1: **Post-Market-Registerstudie: Patients with an implanted Barostim neo-system in accordance with CE-approved criteria for heart failure with reduced ejection fraction. Data regarding heart failure and device function will be collected at 3, 6 and 12 months after activation and will be compared to data prior to the implantation.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary efficacy evaluation will be the following values at six month relative to baseline:

a) change in the extent of heart failure (NYHA class)
b) Quality of Life as measured by the Minnesota Living with Heart Failure Questionnaire
c) assessing the performance of a patient below the anaerobic threshold by using the Six-Minute Hall Walk

Secondary Outcome

Secondary Objectives
1. The following data at 12 months compared to pre-implant baseline:
a. Extend of heartfailure measured by NYHA Class
b. Quality of Life with the Minnesota Living with Heart failure Questionnaire
c. Performance of the patient assed with the Six-Minute Hall Walk
d. Biomarker for grade of heart falure (NT-pro-BNP)
e. Heartfunction assessed with Left ventricular ejection fraction (LVEF)
2. The rate of all-cause mortality and cardiovascular mortality at 12 months
3. The following data at 12 months compared to to the 12 months period pre-implant:
a. Heart failure hospitalization
b. Number of episodes
c. Total days hospitalized
d. Total cost of hospitalization
e. Incidence of ventricular and atrial tachyarrhythmias

Countries of recruitment

- DE **Germany**
- IT **Italy**

Locations of Recruitment

- Medical Center **Meizinische Hochschule Hannover, Hannover**
- Medical Center **Asklepios Klinik Altona, Hamburg**
- Medical Center **UKMG, Göttingen**
- Medical Center **Uniklinik, Gießen**
- Medical Center **Uniklinik, Köln**
- Medical Center **Uniklinik, Leipzig**
- Medical Center **Uniklinik, Campobasso**
- Medical Center **Herz und Diabeteszentrum, Bad Oeynhausen**
- Medical Center **Klinikum St. Georg, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/04/07**
- Target Sample Size: **500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

To be eligible for this registry, subjects must meet all of the following inclusion criteria:
1. Implanted with the Barostim Neo system per the CE-Mark approved criteria for heart failure at any time in the past.
2. On stable, maximally-tolerated, guideline-directed heart failure medications for at least 30 days prior to implant, where stable is defined as:
• No more than a 100% increase or a 50% decrease of the dosage of any one medication other than a diuretic.
• Medication changes within a drug class are allowed as long as the equivalent dosage is within the limits specified above.
• Unrestricted changes in diuretics are allowed as long as the subject remains on a diuretic.
3. Signed a CVRx-approved informed consent form for the registry.

Exclusion criteria

Patient does not meet inclusion criteria

Addresses

- **Primary Sponsor**

  CVRx Incorporated
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  MN 55445 Minneapolis
  United States

  Telephone: **[---]***
  Fax: **[---]***
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  URL: **[---]***

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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United States

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*