Rheos Diastolic Heart Failure Trial

Published: 01-10-2008
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The purpose of this clinical investigation is to describe the safety and efficacy of the Rheos Baroreflex Activation Therapy System in subjects with diastolic heart failure.

Ethical review	Not approved
Status	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON32245

Source
ToetsingOnline

Brief title
CVRx DHF trail

Condition

- Heart failures

Synonym
Diastolic heart failure, Heart failure with preserved ejection fraction.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: CVRx, Inc., 9201 West Broadway Avenue, Suite 650, Minneapolis, MN, ,CVRx;Inc.;9201 West Broadway Avenue;Suite 650;Minneapolis;MN;USA 55445

Intervention

Keyword: Baroreflex activation therapy, Diastolic heart failure

Outcome measures

Primary outcome

1 Primary Efficacy Objectives

To describe the effects of the Rheos Baroreflex Activation Therapy System on the left ventricular mass index (LVMI) at six months post-randomization.

2. Primary Measures of Safety

To assess the safety of Rheos Baroreflex Activation Therapy System by evaluating all adverse events and estimating the serious system and procedure related adverse event rate through six months post-implant.

Secondary outcome

1. To assess the difference between randomization groups in blood pressure changes from pre-implant between the Rheos ON and Rheos OFF arms at 3 and 6 months post-randomization.

2. To assess the difference between randomization groups in the increase in the six-minute hall walk distance at 3 and 6 months post-randomization.

3. To assess the difference between randomization groups in changes in E/e* from pre-implant between the Rheos ON and Rheos OFF arms at 3 and 6 months post-randomization.

4. To assess the difference between randomization groups in the improvement in the Minnesota Living with Heart Failure Questionnaire index score at 3 and 6 months post-randomization.

5. To assess the differences between randomization groups in the reduction in

NT-pro-BNP at 3 and 6 months post-randomization.

Study description

Background summary

Heart failure has become an increasingly important public health issue, reaching epidemic proportions. With an increasing incidence and prevalence, and an aging population, it is expected that the heart failure epidemic will only worsen. Heart failure can be divided into two clinical subsets based primarily on left ventricular ejection fraction (LVEF). Systolic heart failure patients present with large dilated hearts and low ejection fractions (EF) of < 45% and heart failure symptoms and LVEF * 45% termed diastolic heart failure (DHF). Approximately half of all heart failure patient are diastolic heart failure patients. Desite recent advances in stadard heart failure treatment its prognosis remains poor with 5-year survival rates of 43%. And following heart failure hospitalization up to 20% mortality at one year. A novel treatment option for these patients is the "Rheos baroreflex activation therapy" system. Which increases afferent signals to these medullary centers causing a reduction in sympathetic tone. Lowered sympathetic tone results in lower heart rate, diuresis, and vasodilatation all of which function to reduce blood pressure and potentially alleviate heart failure symptoms.

Study objective

The purpose of this clinical investigation is to describe the safety and efficacy of the Rheos Baroreflex Activation Therapy System in subjects with diastolic heart failure.

Study design

a prospective, randomized trial.

Intervention

implant Rheos : ON and OFF arms

Study burden and risks

The potential risks associated with this study are the known risks of surgery, anesthesia, and baroreflex stimulation. Although the risk involved with anesthesia and surgery is increased in the heart failure population, the sponsor and the investigators have determined that this study is justified

because of the potential benefit of the CardioFit* treatment on patient's heart failure symptoms and prognosis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Be at least 21 years of age.
2. Have bilateral carotid bifurcations that are below the level of the mandible.
3. Have a left ventricular ejection fraction * 45% within 30 days of enrollment.
4. Within 24 months prior to enrollment, hospital admission for heart failure or at least 2 of the signs/symptoms of heart failure that resolved on heart failure treatment.
5. NYHA Class II-III classification within 30 days prior to enrollment
6. Have an office cuff systolic blood pressure greater than or equal to 140 mmHg within 30 days prior to enrollment.

Exclusion criteria

1. Have known or suspected baroreflex failure or autonomic neuropathy.
2. Have an arm circumference greater than 46 cm and/or a body mass index of greater than 45.
3. Have significant uncontrolled symptomatic bradyarrhythmias with a heart rate < 60 bpm.
4. Significant orthostatic hypotension.
5. Had a myocardial infarction or cerebral vascular accident within 3 months prior to enrollment.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Ethics review

Not approved

Date:	01-10-2008
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL22862.068.08