A Prospective, Multicenter, Open Label, Single Arm, Study to Assess the Safety & Performance of the Harmony Aortic Stimulation System (HASS) for the Treatment of Heart Failure

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Evaluate the performance and safety of HASS 200 (HARMONY AORTIC STIMULATION SYSTEM) in treatment of heart failure subjects.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON51726

Source
ToetsingOnline

Brief title
ENDO-HF

Condition

- Heart failures

Synonym
Cardiac Failure, Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: van de Wetering CRC
Source(s) of monetary or material Support: Enopace Biomedical

Intervention

Keyword: Endovascular, Neuromodulation, Treatment heart failure

Outcome measures

Primary outcome

The occurrence of all system and/or procedure related adverse and serieus

adverse events up until 6 months post treatment activation

Secondary outcome

The assessment of change in the heart function after implant of the device.

Study description

Background summary

The purpose of the study is to evaluate the performance and safety of HASS 200 (HARMONY AORTIC STIMULATION SYSTEM) in treatment of heart failure subjects. Stimulation of the aorta has been shown in anima! testing to reduce the heart pressure which may allow the heart to work easier. Enopace HASS is an experimental device designed to stimulate the aorta. There are commercially available stimulation devices in the market that are used to treat
Enopace concept involving the stimulation of the aorta tor the treatment of heart failure patients was tested in 12 patients enrolled in a European study. In this study, patients like you who had congestive heart failure, had their aorta stimulated tor a short time (approximately 15 minutes) by means of a temporary catheter. The stimulation was well tolerated, safe with a positive change in heart pressure.

Study objective

Evaluate the performance and safety of HASS 200 (HARMONY AORTIC STIMULATION SYSTEM) in treatment of heart failure subjects.

Study design

A Prospective, Multicenter, Open Label, Single Arm, Study to Assess the Safety & Performance of the Harmony Aortic Stimulation System (HASS) for the Treatment of Heart Failure

Intervention

Implant sent-like medical device HASS in aorta

Study burden and risks

1. Screening
2. Baseline measurements
3. Device implantation
4. Treatment initiation (approximately 30 days after implantation)
5. Treatment at home during the day time which includes wearing the Patient Unit
6. Attending three follow up sessions after 1, 3 and 6 months
7. Following, visiting the hospita! every 6 months up to 5 years

Potential long term lmplant Unit related Risks
These risks may include, but are not limited to: arterial dissection/perforation (tear/poke in the arterial wal!), hemothorax / pneumothorax (collection of blood or air in the chest), infection, fever, hematoma or seroma [collection of blood/fluid in the implanted area], blood clotting at the implant site, embolie phenomena (stroke, myocardial infraction and peripheral arterial occlusion with end organ damage).
The long term effects of having a stent-like device that electrically activating the aorta, and/or its long term reliability, are not welf known in patients with heart failure.

Pregnancy (risk to fetus)
Pregnant women are excluded trom this study. The risks of the HASS system to the fetus/ embryo or are unknown.

Unknown Risks
This treatment may involve some additional risks to you, the nature of which are not yet known. In addition, it is possible that the HASS treatment may worsen your condition.

Potential rare side effects
Following are side effects reported among heart failure patients who used other stent/ blood vessel implanted stimulators or neurostimulators: angina pectoris (chest pain) or palpitations, ankle edema (swelling due to water weight), body rejection phenomena including local tissue reaction, diarrhea and/or constipation, dizziness/lightheadedness and/or syncope (fainting), dyspepsia (upset stomach), dysphagia (difficulty swallowing), dyspnea (Shortness of

breath), fatigue, headache, hyperkalemia or hypokalemia (too much or too little potassium), increased cough, insomnia (difficulty sleeping), irritation of the larynx (especially in smokers), myalgia (pain in the muscles), nausea and/or vomiting, pain (abdominal, back, or other), pain/discomfort from stimulation (such as jaw, head, tooth), twitch (rapid contraction and relaxation of a muscle), voice alteration, hoarseness, priapism (uncontrolled prolonged penile erections).

In addition, the following effects were reported among users of other stent/ blood vessel implanted stimulators or neurostimulators for reasons other than heart failure: hypertension (high blood pressure), hypotension (low blood pressure), ataxia (an abnormal walk or gait), depression and obstructive sleep apnea and artifact effects on ECG monitors. Most of these risks were minor, reversible and welf tolerated.
The usual risks for heart failure are also possible, such as heart attacks, stroke and death.
Risks of a blood draw include pain and bleeding, bruising, discomfort and/or infection at the injection site, or temporary dizziness. There may be side effects that are not known at this time.
The Harmony therapy may result in a decrease in the patient's heart failure symptoms and a slowing of the progression of their disease. lt can potentially improve heart performance and increase their overall health and quality of life.

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. Subject is at least 18 years old but no more than 85 years old
2. Subject is a male or a postmenopausal female, or a female of childbearing age for whom pregnancy was excluded and who has accepted to use adequate contraception measures for the entire study duration
3. Subject is diagnosed as chronic heart failure NYHA class II-III.
4. Heart Failure is accompanied by:
For HFrEF Subjects (must meet at least one of the following):
* BMI-corrected NT-proBNP> 300pg/ml.
* BMI-corrected NT-proBNP*450 pg/ml if persistent atrial fibrillation is evident.
For HFpEF subjects (must meet at least one of the following):
* BMI-corrected NT-proBNP> 300pg/ml.
* BMI-corrected NT-proBNP*450 pg/ml if persistent atrial fibrillation is evident.
* PCW at rest >15 mmHg
* PCW at exercise > 25 mmHg
For BMI corrected NT-proBNP see appendix E
5. Subject should be on stable, maximally-tolerated, guideline-directed cardiovascular medications for at least 30 days prior to enrolment.
6. Subject has an average heart rate between 60 and 110 b/min recorded in a 24-h Holter measurement.
7. Subject is capable to walk a distance of 150-450 m in 6 minutes hall walk test.
8. Subject is willing to and capable of providing informed consent.
9. Subject is capable of participating in all tasks associated with this clinical investigation.
10. Subject can comply with catheterization lab standard of care procedures.

Exclusion criteria

1. Subject has a Cardiac Resynchronization Therapy (CRT) or is a candidate

within the next 6 months to have one
2. The subject has a permanent pacemaker and is 100% pacemaker dependent.
3. Subject has an Implantable Cardioverter Defibrillator (ICD) and/or any other active electrical implant that is found to be affected by the Harmony System operation in a compatibility assessment performance.
4. Subject has significant uncontrolled symptomatic bradyarrhythmias or unstable ventricular arrhythmias.
5. Subject has a 1st degree AV block with PR interval > 240msec, 2nd or 3rd degree AV block.
6. Subject has severe Chronic Obstructive Pulmonary Disease (COPD) or severe restrictive lung disease (e.g., requires chronic steroid use or home oxygen use)
7. Subject has a Body Mass Index (BMI) * 40 kg/m2
8. Subject with renal insufficiency (eGFR<25 ml/min/1.73 m2)
9. Subject has thoracic aorta*s abnormalities or diseases (e.g. aneurysm, dissection, extensive plaque, implanted stent or stent graft)
10. Subject's thoracic aorta*s anatomy is not compatible with the Harmony*s implant (e.g. aortic diameter or morphology) based on CT scan analysis.
11. Subject*s thorax anatomy does not enable adequate communication between implant and the external patient unit based on CT scan analysis.
12. Subject diagnosed with severe valvular (Mitral or Aortic) disease (e.g. severe stenosis or regurgitation).
13. Subject with prior cardiac transplant or heart transplant candidate.
14. Subject with unstable angina, myocardial infarction, percutaneous transluminal coronary angioplasty, cerebral vascular accident, transient ischemic attack or coronary artery bypass graft within 90 days prior to enrolment.
15. Subject expected to undergo cardiac surgery or percutaneous cardiac intervention (e.g. coronary and valves) during the study period.
16. Subject whose heart failure is due to congenital heart disease.
17. Subject is unable to take anticoagulants or antiplatelet agents.
18. Subject has infiltrative or restrictive cardiomyopathy.
19. Subject diagnosed with Marfan syndrome.
20. Subject is allergic to iodine or contrast media.
21. Subject has diseases or conditions which, in the judgment of the PI, preclude participation in the clinical investigation.
22. Subject with a life expectancy of less than 12 months, per PIs' decision.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2023
Enrollment:	5
Type:	Actual

Medical products/devices used

Generic name:	Harmony Aortic Stimulation System (HASS)
Registration:	No

Ethics review

Approved WMO Date:	08-07-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL80987.000.22

Study results

Date completed: 03-08-2023

Actual enrolment: 2

Summary results
Trial is onging in other countries