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	Will not start
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON46909

Source
ToetsingOnline

Brief title
ENDO-HF

Condition

- Heart failures

Synonym
Cardiac Failure, Heart Failure

Research involving
Human

Sponsors and support

Primary sponsor: ENOPACE BIOMEDICAL LTD.
Source(s) of monetary or material Support: Enppace Biomedical

Intervention

Keyword: Endovascular, Heart failure, NeuromoDulation, Treatment

Outcome measures

Primary outcome

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

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 animal 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 for 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 for 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

A patient participating in the study undergoes the following steps:
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 hospital every 6 months up to 5 years

Potential long term Implant Unit related Risks
These risks may include, but are not limited to: arterial dissection/perforation (tear/poke in the arterial wall), 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, embolic 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 well known in patients with heart failure.

Pregnancy (risk to fetus)
Pregnant women are excluded from 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 well 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. It 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

Inclusion Criteria
1. Subject at least 18 years of age 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. Subject is treated with diuretic(s) for heart failure *30 days prior to study entry
5. Subject has no other noncardiac disease that could account for his/her dyspnea
6. For a subject with left ventricular ejection fraction (LVEF) * 40% all of the following must be present:
a) Left atrial enlargement > 25 cm2;
b) LA volume index * 40ml/m2;
c) Left ventricular hypertrophy as documented by echocardiogram with LVEDVI < 97 mL/m2;
d) NT-proBNP > 300 pg/mL
7. For a subject with left ventricular ejection fraction (LVEF) < 40%, subject has an elevated NT-proBNP >300
8. Subject should be receiving optimal medical treatment with no change in treatment in the previous 3 months (90 days) from enrolment with the exception of diuretic dosage; Optimal drug therapy as per current ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure . Subject has an average heart rate between 60 and 110 b/min recorded in a 24-h Holter measurement.
9. Subject is capable to walk a distance of 150-550 m in 6 minutes hall walk test.
10. Subject is willing to and capable of providing informed consent
11. Subject is capable of participating in all testing associated with this clinical investigation
12. Subject can comply with catheterization lab standard of care procedures

Exclusion criteria

Exclusion Criteria
1. Subject has been hospitalized for heart failure, diabetes or COPD within 30 days prior to enrolment
2. For a subject with left ventricular ejection fraction (LVEF) * 40%, the presence of chronic pulmonary disease requiring home oxygen therapy, oral steroid therapy, or hospitalization for exacerbation within 12 months of study entry, or significant chronic pulmonary disease in the opinion of the investigator
3. Subject with unstable angina, myocardial infarction, PTCA or coronary artery bypass graft within 180 days prior to enrolment
4. Subject with cerebral vascular accident or transient ischemic attack within 180 days prior to enrolment
5. Subject has resistant hypertension with systolic blood pressure * 180 mmHg within 30 days prior to enrolment
6. Subject has severe sclerosis or calcification of the thoracic aorta, as seen in CT scan
7. Subject has thoracic aorta abnormalities or disease e.g. aneurysm, dissection, extensive plaque, or implanted stent or stent graft, as seen in CT scan
8. Subject's anatomy is not compatible with the Harmony System, including that the aorta does not meet the appropriate anatomy (size and morphology) for implant placement based on Computed Tomography (CT) analysis.
9. Subject who has thoracic anatomy that does not enable adequate communication between implant and external unit as calculated by analyzing the CT scan, shall be excluded.
10. Subject diagnosed with severe aortic valve disease (severe aortic stenosis or aortic regurgitation)
11. Subject has severe mitral stenosis or grade 4 mitral regurgitation
12. Subject expected to undergo cardiac surgery during the study period
13. Subject whose heart failure is due to congenital heart disease
14. Subject diagnosed with Marfan Syndrome
15. Subject with moderate or severe chronic obstructive lung disease
16. Subject with renal insufficiency (eGFR<35)
17. Subject is allergic to iodine or contrast media
18. Subject is unable to take anticoagulants or antiplatelet agents
19. Subject has a 1st degree AV block with PR interval > 240msec, 2nd or 3rd degree AV block
20. Subject has history of brady-tachy arrhythmias
21. Subject with prior cardiac transplant or heart transplant candidate
22. Subject has infiltrative or restrictive cardiomyopathy
23. Subject had a vagotomy procedure in the past
24. Subject has a Body Mass Index (BMI) > 40 kg/m2
25. Subject with a life expectancy of less than 12 months, per physician judgment
26. Subject is a candidate within the 6 month follow up period for, or already has, a CRT and/or permanent pacemaker and is 100% pacemaker dependent
27. Subject who has an implantable cardioverter defibrillator that is affected by the Harmony System operation based on compatibility assessment during screening
28. Subject using any other medical electrical device

29. Subject involved in any concurrent clinical investigation
30. Subject has diseases or conditions which, in the judgment of the investigator, preclude participation in the clinical investigation

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

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

Medical products/devices used

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

Ethics review

Approved WMO Date:	10-06-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-10-2016
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	29-10-2018
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Not approved Date:	04-03-2022
Application type:	Amendment
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	NL55898.100.15