HEMOdynamic guidance with CardioMEMS in LVAD patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24459

Source
Nationaal Trial Register

Brief title
The HEMO-VAD study

Health condition

The study population for this clinical investigation (pilot feasibility study) is advanced heart failure NYHA class III patients with dyspnea upon mild physical activity, or NYHA class IV patients who are refractory to advanced heart failure management and scheduled for semi-elective or elective LVAD implantation (INTERMACS class 2-5).

The CardioMEMS device has been studied in chronic heart failure patients but not in LVAD patients. With permission of the company, we study this new patient groups. The sensor is impanted in patient with chronic heart failure before LVAD implantation.

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: A research grant has been granted by St Jude Abbott to perform this study which only partly covers total costs. Permission was obtained from the company to study the devices (CardioMEMS PA sensor and Heartmate-III LVAD) by St Jude Abbott in this patient group.

Intervention

Outcome measures

Primary outcome

To investigate the effectiveness and potential of the hybrid construction between CardioMEMS PA senseor and HeartMate-III LVAD device

The number of HF hospitalizations

Secondary outcome

Post-hoc analyses will be performed to study pulmonary hypertension and its potential reversibility during LVAD treatment. Additionally, we will study heart rate detection with cardioMEMS during LVAD treatment and the incidence of VTs. Additionally, we will study renal function and urinary measurements during follow-up with LVAD treatment in relation to PA pressure, and Rv function.

Study description

Background summary

The HEMO-VAD study will assess clinical management of HeartMate 3 LVAD patients guided by hemodynamic parameters provided by the CardioMEMS HF System as a clinical hybrid construction to optimize patient outcome and reduce HF hospitalizations and complications of LVAD therapy. The current study is a prospective single-centre observational pilot study investigating the feasibility of hemodynamic guidance by CardioMEMS in LVAD care. Data will be collected on functional status, health care utilization and clinical (safety) outcomes. The study population for this clinical investigation is advanced HF NYHA class III patients with dyspnea upon mild physical activity, or NYHA class IV patients who are refractory to advanced HF management and scheduled for semi-elective or elective LVAD implantation (INTERMACS class 2-5).

Study objective

1. testing the feasibility of the use of an hybrid construction of a CardioMEMS PA sensor and HeartMate III LVAD therapy (with permission of the company Abbott).

2. Hemodynamic guidance improves patient outcome and HF hospitalizations by early detection of complications

Study design

follow-up of 1 year

Intervention

Hemodynamic guidance by CardioMEMS PA sensor

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

• Signed Informed Consent Form (ICF)

• Age ≥18 years

• LVEF <25%

• NYHA Class III with dyspnea upon mild physical activity or NYHA Class IV with INTERMACS classes 2-5

• Scheduled or intended for LVAD implantation within 2 weeks

• Body surface Area >= 1.2 m2 and chest circumference, at the axillary level, of less than 65 inches if BMI >35 kg/m2

• Females of child bearing age must agree to use adequate contraception and at inclusion negative pregnancy test

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

• No written informed consent

• patients with contra-indications for the PA pressure sensor device, which will include active infection, a history of deep vein thrombosis or recurrent pulmonary embolism,

• unable to tolerate right heart catheterization

• Intolerance to anticoagulant or antiplatelet therapies or any other peri/post-operative therapy the investigator will require based upon the patients' health status

• patients with a known coagulation disorder or hypersensitivity to aspirin.

• History of pulmonary embolism within 30 days prior to enrollment or history of recurrent (>1 episode) pulmonary embolism and/or deep vein thrombosis

• Fixed pulmonary hypertension with a most recent PVR ≥ 8 Wood units that is unresponsive to pharmacologic intervention (which makes CardioMEMS sensor no additive value)

• History of stroke within 90 days prior to enrollment, or a history of cerebrovascular disease with significant (> 80%) uncorrected carotid stenosis

• Serum creatinine ≥ 221 umol/L or eGFR below 25 or the need for chronic renal replacement therapy

• Psychiatric disease/disorder, irreversible cognitive dysfunction or psychosocial issues that are likely to impair compliance with the study protocol and LVAS management

• patients with mechanical right heart valves,

• INTERMACS 1 emergency LVAD implantations.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2017
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-11-2017
Application type:	First submission

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
NTR-new	NL6627
NTR-old	NTR6804
Other	: METC 2017-342

Study results

Summary results

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