HEMOdynamic guidance with CardioMEMS in LVAD patients

Gepubliceerd: 08-11-2017 Laatst bijgewerkt: 18-08-2022

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…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24459

Bron
Nationaal Trial Register

Verkorte titel
The HEMO-VAD study

Aandoening

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.

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: 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.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

The number of HF hospitalizations

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

follow-up of 1 year

Onderzoeksproduct en/of interventie

Hemodynamic guidance by CardioMEMS PA sensor

Contactpersonen

Publiek

Department of Cardiology, Erasmus MC Thoraxcenter

J.J. Brugts
s gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
+31614229373

Wetenschappelijk

Department of Cardiology, Erasmus MC Thoraxcenter

J.J. Brugts
s gravendijkwal 230

Rotterdam 3015 CE
The Netherlands
+31614229373

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2017
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-11-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6627
NTR-old	NTR6804
Ander register	: METC 2017-342

Resultaten

Samenvatting resultaten

-