HEMOdynamic guidance with PA-sensor CardioMEMS in patients with an left ventricular assist device (LVAD)

Published: 27-07-2017
Last updated: 13-04-2024

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

Summary

ID

NL-OMON46145

Source
ToetsingOnline

Brief title
HEMO-VAD pilot

Condition

- Heart failures

Synonym
endstage heartfailure, LVAD implantation

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,De afdeling cardiologie van het Erasmus MC verricht en financieert dit onderzoek zelf (1e geldstroom);en

heeft mede-financiering gezocht bij de firma St.Jude/Abbott met een onderzoeksbijdrage die de kosten gedeeltelijk dekt (3e geldstroom);zie G2. ,St. Jude Medical

Intervention

Keyword: CardioMEMS, Hemodynamic monitoring, LVAD

Outcome measures

Primary outcome

To demonstrate the feasibility of using hemodynamic guidance by the PA sensor

in LVAD HM-III patients.

Secondary outcome

- investigate whether the use of CardioMEMS PA sensor in HeartMate-III LVAD

patients improves outcome, reduce complications and reduce HF hospitalizations

- to study detected hemodynamic effects in case of LVAD associated

complications such as RV failure, pump thrombosis, gastro-intestinal bleeding

or pump infection

- to study the reversibility of pulmonary pressures and pulmonary hypertension

during LVAD therapy

Study description

Background summary

Advanced heart failure and LVAD treatment is complex and associated with strongly elevated risk of postoperative complications as well as high rates of re-hospitalizations. Currently, the LVAD pump only provides basic data and clear hemodynamic feedback is lacking. There is a strong clinical demand for guidance of therapy in these patients. Hemodynamic guidance may improve the pre-operative phase by delivering the patient in a more optimal condition to surgery. Also, it may improve peri- and postoperative fluid management and detect complications in an earlier stage. Hemodynamic feedback is now possible

with the CardioMEMS sensor, even at home.

Study objective

The objective of this clinical investigation is to assess and characterize the 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.

Study design

The current study is a prospective single-centre observational 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.

Study burden and risks

The implantation of the CardioMEMS sensor is a relatively small procedure with risk comparable to the regular right heart catheterization (occurring in all patients). The main burden of the CardioMEMS sensor is the femoral venous puncture with associated bleeding complications at entry site. Patient must tolerate a routine Swan Ganz measurement (right heart catheterization), which will be a procedure of 30 minutes and comply with the daily pressure recordings of 18 seconds. The out-patient clinic follow-up scheme is comparable to standard care. The device has been shown to be reliable and safe in the CHAMPION trial with 1.4% complication rate which were all minor and manageable. The risk-to-benefit ratio is extremely low as reported in the CHAMPION trial with a reduction in HF hospitalizations by about 40% with virtually no major device related complications. The device has been approved by FDA and is CE marked and clinically available.

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

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

Exclusion criteria

*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,
*Patients unable to tolerate right heart catheterization
*Intolerance to anticoagulant or antiplatelet therapies
*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 LVAD management
*Patients with mechanical right heart valves,
*INTERMACS 1 emergency LVAD implantations.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-11-2017
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	CardioMEMS
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	27-07-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL61544.078.17