Hemodynamic Monitoring with the CardioMEMS PA sensor and Quality of Life in Patients with Chronic Heart Failure: The MONITOR HF Trial

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

Summary

ID

NL-OMON52937

Source
ToetsingOnline

Brief title
MONITOR HF Trial

Condition

- Heart failures

Synonym
heart failure, pump dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Abbott,Ministerie van VWS

Intervention

Keyword: cardiomems, decompensation, heart failure, pulmonary pressure

Outcome measures

Primary outcome

Quality of life: assessments will be performed using KCCQ questionnaires at baseline (t=0), either signing informed consent or at admission for the actual implantation of the device, and at follow-up intervals of 3, 6, and 12 months follow-up after randomization in both treatment arms. Primary analysis is based on KCCQ at 6 months and 12 months.

a. Short-term assessment (6 months)

b. Long-term assessment (12 months)

Secondary outcome

The number of HF-hospitalizations in patients randomized to CardioMEMS HF-system compared to the patients randomized to standard care during follow-up. The definition of a HF hospitalization is an admission longer than 6 hours and/or the need of intravenous diuretics for decongestion of the patient. Minimal follow-up will be 12 months for last patient included.

Other secondary endpoints will be all-cause mortality; days alive outside of the hospital, days admitted in the hospital, number of total hospital presentations (out-patient clinic, clinical and emergency department) and change in baseline PA pressure. Duration of HF hospitalization. Number of medication changes. Additionally, all endpoints will be related to KCCQ health

scores changes. Costeffectiveness wil be calculated using the EQ-5D-5L.

Study description

Background summary

Remote monitoring of PA pressures is available with the CardioMEMS PA sensor. Measuring filling pressures in HF patients can be a way to further improve outcome and quality of life by intervening before symptoms or weight gain occurs keeping the patient out of the hospital.

CardioMEMS is not reimbursed in the Netherlands and only available for scientific purposes. Zorginstituut and the Ministry of Health have granted a conditional coverage study project considering the highly promising level of care provided by CardioMEMS monitoring in heart failure patient. If proven effective in the Dutch health care system, CardioMEMS is covered and reimbursed by health care insurance in the Netherlands. Through this conditional coverage initiative, novel promising care is more readily available to chronic HF patients. The current study design has been set up to answer the questions at hand for the Ministry of Health. If proven effective and cost-effective in the Netherlands, CardioMEMS PA monitoring can be requested to be extend from conditional coverage in clinical trial setting towards complete reimbursement in the Dutch health care system.

Study objective

We hypothesize that the CardioMEMS HF system will be safe and superior to standard care in improving the quality of life and health status in patients with chronic HF in the Netherlands. Additionally, we hypothesize the CardioMEMS HF system is cost-effective in a Dutch heart failure care program (assessed with KCCQ, EQ5D5L and reduction in HF hospitalizations).

Study design

The MONITOR HF trial is an investigator initiated, national multicentre randomised clinical trial enrolling 340 patients with chronic HF NYHA class III and at least 1 HF hospital admission in the previous 12 months.

Active comparator: standard of HF-care management plus CardioMEMS PA-monitoring with a treatment algorithm for hemodynamic assessments
Control group: standard practice based HF care

Intervention

Intervention group: implantation CardioMEMS device, incl baseline measurement of pulmonary pressures (swann ganz cath).
Control group: standard clinical care (according to guidelines).

Study burden and risks

Implantation of the CardioMEMS HF System may offer certain advantages. Studies to date have demonstrated a reduction in HF-related hospitalizations and improved quality of life in patients using the CardioMEMS HF System when compared with patients receiving standard care. Risks associated with the implantation and use of the device is minor, generally without serious consequences, and occurs at a low rate. The actual risk associated only with the deployment of the device is low. The CHAMPION clinical trial reported no pressure sensor failures, and device/system related complications occurred in only 1.4 % of the cases (n=8) with the vast majority related to manageable bleeding complications at the entry site (venous puncture)

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Written informed consent obtained from subject aged >18 years
2. Diagnosis of NYHA-Class III heart failure with at least 1 (additional) HF hospitalization within 12 months of baseline visit (independent of EF %)
3. Subjects with reduced EF (HFrEF) should be treated according to National and International (ESC) guidelines for optimal or maximum tolerated doses of HF medication and evaluated for ICD or CRT-D therapy if indicated.
4. Subjects with a BMI <=35. Subjects with BMI >35 will require their chest circumference to be measured at the axillary level <65 inches (related to distance of the sensor)
5. Subjects willing and able to comply with the follow-up requirements of the study

Exclusion criteria

1. Subjects with an active infection
2. Subjects with history of recurrent (>1) pulmonary embolism or deep vein thrombosis
3. Subjects who have had a major cardiovascular event (e.g., myocardial infarction, open heart surgery, stroke) within 2 months
4. Subjects with Cardiac Resynchronization Device (CRT) implanted <3 months prior to enrolment and implantation of the sensor (in order to avoid manipulation of lead)
5. Subjects with a Glomerular Filtration Rate (GFR) <25 ml/min (obtained within 2 weeks of the baseline visit), refractory to diuretic therapy or on chronic renal dialysis
6. Subjects with complex congenital heart disease or mechanical right heart valve(s)
7. Subjects is scheduled for or likely to undergo heart-transplantation or VAD within 6 months of baseline visit
8. Subjects with known coagulation disorders or allergy to aspirin, and/or clopidogrel.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	11-04-2019
Enrollment:	340
Type:	Actual

Medical products/devices used

Generic name:	CardioMEMS
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-01-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	18-02-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	29-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	21-06-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	15-11-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-07-2022
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	12-12-2022
Application type:	Amendment
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

ID: 28853
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL67334.078.18

Register	ID
OMON	NL-OMON28853