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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28853

Source
Nationaal Trial Register

Brief title
MONITOR HF

Health condition

Patients with chronic heart failure in NYHA functional class III with 1 or more HF hospitalization (>6 hours admission or need of iv diuretics) in the past 12 months.

Sponsors and support

Primary sponsor: Erasmus University Medical Center

Voorwaardelijke toelating tot basispakket zorg 2019 procedure via Zorginstituut en VWS.
Source(s) of monetary or material Support: Voorwaardelijke toelating tot basispakket zorg 2019 procedure via Zorginstituut en VWS tav zorgkosten, Abbott tav studiekosten.

Intervention

Outcome measures

Primary outcome

Quality of life (KCCQ questionnaires)

Secondary outcome

HF hospitalizations
Cost effectiveness

Study description

Background summary

Rationale: Remote monitoring of PA pressures is available with the CardioMEMS PA sensor. Measuring hemodynamic congestion with filling pressures instead of clinical congestion in HF patients can be a way to further improve quality of life and clinical outcome by intervening before symptoms or weight gain occurs.
Objective: to demonstrate efficacy and cost-effectiveness of CardioMEMS PA monitoring on top of standard heart failure care in the Netherlands.

Study design: The current study is a prospective multi-centre randomised clinical trial investigating the quality of life in patients treated with the CardioMEMS PA sensor versus standard HF care in the Netherlands. Data will be collected on functional status, health care utilization and clinical (safety) outcomes.

Study population: The study population consists of chronic HF patients in functional NYHA class III and at least 1 hospitalization for heart failure (documented longer than 6 hours and/or use of iv diuretics for congestion) in the previous 12 months before enrolment.

Intervention: At study entry, patients are randomised to standard heart failure care (n=170) or the CardioMEMS PA monitoring system (n=170) in a 1:1 ratio. Patients will be studied for at least 1 year of follow-up, with maximum follow-up 36 months. Pulmonary artery pressure data will be utilized to guide adjustments of medical therapy (e.g., diuretics, vasodilators) with a treatment algorithm guidance on top of standard care which exists of monitoring patients' weight and symptoms.

Main study parameters/endpoints: The primary endpoint of this study is the improvement in quality of life as measured by the KCCQ heart failure questionnaire. Secondary endpoints are the reduction in the number of HF hospital admissions during follow-up and the improvement in health status assessed by EQ5D5L questionnaire including a cost-effectiveness analysis in the Dutch health care system.

Study objective

To investigate whether CardiOMEMS PA monitoring improves quality of life, reduces HF hospitalizations and is cost-effective in patient with chronic heart failure in the Netherloands

Study design

Start 01.04.2019

Inclusion period 2 years scheduled

Follow-up minimum 12 months last patient included

Intervention

CardioMEMS PA monitoring

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:

1. Written informed consent obtained from subject aged >18 years

2. Diagnosis of chronic heart failure in NYHA functional Class III with at least 1 HF hospitalization within 12 months of baseline visit

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 and able to comply to the daily readings
*) definition of HF according the ESC guidelines 2016 for HFrEF HFmEF and HFpEF

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 with known pulmonary arterial hypertension (WHO category 1 or 4/5) were PA pressure are most likely not responsive to cardiac treatment.

8. Subjects is scheduled for or likely to undergo heart-transplantation or VAD within 6 months of baseline visit

9. 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:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2019
Enrollment:	340
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52937
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7430
NTR-old	NTR7672
CCMO	NL67334.078.18
OMON	NL-OMON52937

Study results

Summary results

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