# CardioMEMS European Monitoring Study for Heart Failure

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Heart failures |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON45748

**Source**
ToetsingOnline

**Brief title**
MEMS HF

### Condition

- Heart failures

**Synonym**
decompensation, Heat failure

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** St. Jude Medical
**Source(s) of monetary or material Support:** St Jude Medical en de afdeling cardiologie van de deelnemende ziekenhuizen

## Intervention

**Keyword:** CardioMEMS sensor, Hart Failure, Pulmonary Artery Pressure

## Outcome measures

### Primary outcome

Primary Safety Endpoints:

The primary safety endpoints are freedom from device/system related complications (Serious Adverse Device Effects) and freedom from pressure sensor failure at 12 months post-implant.

* A device/system related complication (Serious Adverse Device Effects) is an adverse event that is, or is possibly, related to the device/system (wireless pressure sensor or external electronics) and has at least one of the following characteristics:

o is treated with invasive means (other than intramuscular medication or right heart catheterization which is used for diagnostic purposes)

o results in death of the subject

o results in the explant of the device

* A pressure sensor failure occurs when no readings can be obtained after troubleshooting the system to rule out any problems with the external electronics.

Primary Clinical Performance Endpoint:

The primary clinical performance endpoint is patient data transmission success at 12 months post implant.

### Secondary outcome

The secondary endpoint is the annualized HF hospitalization rate at 12 months

compared to the annualized HF hospitalization rate for the 12 months prior to

implant.

# Study description

**Background summary**

Heart failure (HF) is a clinical syndrome characterized by frequent hospitalization, poor quality of life, multiple comorbidities, high mortality and a complex therapeutic regimen. Affected individuals suffer from impairment of functional capacity and have a variety of symptoms such as dyspnea, fatigue, limited exercise tolerance, fluid retention, pulmonary congestion and peripheral edema.
HF is a progressive disease associated with high patient morbidity and mortality and a poor quality of life. Prognosis following a diagnosis of heart failure is poor and 5-year survival rates compare badly with those of most cancers. Heart failure is incurable and while patients may die from other causes not directly linked to heart failure once diagnosed with heart failure, they will not be cured of the syndrome by any currently available therapy.

Estimates of the prevalence and incidence of heart failure vary due to differences in definition and assessment of heart failure, there is no gold-standard assessment to diagnose the presence of the disease. The prevalence of heart failure is generally accepted to be 1-2% of the population in the western world with the incidence approaching 5 * 10 people per 1000 per year. The total population of 28 EU member states by January 2013 was estimated to be 505,674,9655 giving an estimated number of heart failure patients of between five and ten million (1 * 2%) in the EU.
This highly prevalent disease leads to over 1,000,000 hospitalizations each year for decompensation requiring acute medical care. Over 90% of patients hospitalized for heart failure are congested with excess body volume resulting in increased pulmonary artery pressures. Current disease management tools are insensitive in estimating pulmonary artery pressures and are of limited utility in remotely monitoring the patient. New technology development has led to a fully implantable leadless and battery-less sensor that can provide pulmonary artery pressures by remote interrogation from the patient*s home.

The CardioMEMS* HF System consists of a wireless, battery-less pressure sensor implanted into the pulmonary artery and external electronics that power and communicate with the sensor and that transmit pulmonary artery pressure waveforms and measurements to a secure website for physician/health care professional review and patient management.

The CHAMPION trial demonstrated that management of heart failure using pulmonary artery pressure information obtained with the CardioMEMS HF System, in addition to traditional signs and symptoms, reduced HF hospitalizations.

The CHAMPION trial was conducted at 64 U.S. centers and enrolled 550 patients with NYHA Class III heart failure who had been hospitalized for heart failure in the previous year. All patients were implanted with a sensor and then randomized to Treatment (heart failure management on the basis of pulmonary artery pressure and standard of care) or Control (heart failure management on the basis of standard of care). CHAMPION met its primary endpoint of reduction in the rate of heart failure hospitalizations at 6 months with Treatment patients having 28% fewer heart failure hospitalizations compared to Control patients; benefit was sustained with a 37% reduction in heart failure hospitalizations over the full randomized study duration13. All secondary endpoints were met demonstrating reduction in pulmonary artery pressures, reduction in proportion of patients hospitalized for heart failure, increase in days alive outside the hospital and improved quality of life.

**Study objective**

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 of care in the United States. The purpose of this study is to characterize the use of the CardioMEMS HF System when used in a real-world setting.

**Study design**

This study is a prospective, non-randomized, open-label, multi-center, post-market study.

**Intervention**

Implantation of CardioMEMS sensor

**Study burden and risks**

Studies to date have demonstrated a reduction in HF-related hospitalizations and improved quality of life in patients using the CardioMEMS HF System. Risks associated with the implantation and use of the device are minor, generally without serious consequences, and occur at a low rate. The CHAMPION Clinical Trial7 reported no pressure sensor failures, and device/system Related Complications occurred in only 1% of the cases with an additional 1% of the patients experiencing a Procedure-related adverse event. Therefore, there is reasonable evidence that the clinical benefits for this procedure outweigh the risks and thus provide justification for proceeding with this observational

study.

# 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

Indicated to receive a CardioMEMS sensor implant per the CardioMEMS* HF System User*s Manual
o > 18 years of age
o Diagnosis of NYHA Class III Heart Failure at the time of sensor implantation
o Hospitalization for worsening HF within 12 months prior to the CardioMEMS HF System implant. For the purposes of this study, a HF hospitalization is defined as an overnight stay in the hospital with signs and symptoms of congestion requiring intensification of treatment for HF
o Subjects with reduced Left Ventricular Ejection Fraction (LVEF) must be on stable Guideline

Directed Medical Therapy (GDMT) as tolerated
o Written informed consent obtained from subject

### Exclusion criteria

* Known coagulation disorders or inability to take two types of blood thinning medications for one month after the sensor is implanted
* Subjects deemed a candidate for transplant, Ventricular Assist Device, or hospice care in the next 12 months or are otherwise not expected to be able to complete the study follow up

## Study design

### Design

**Study type:** Interventional

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 28-12-2016 |
| Enrollment: | 35 |
| Type: | Actual |

### Medical products/devices used

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|---|---|
| Generic name: | Implantation of CardioMEMS sensor |
| Registration: | Yes - CE intended use |

## Ethics review

Approved WMO

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| Date: | 07-09-2016 |
| Application type: | First submission |

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| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 26-10-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 21-12-2016 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 24-02-2017 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |
| Approved WMO Date: | 27-11-2017 |
| Application type: | Amendment |
| Review commission: | METC Amsterdam UMC |

# 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 | NL56816.018.16 |