Trial to Evaluate Safety And Effectiveness of Mechanical Circulatory Support in Patients with Advancing Heart Failure (TEAM-HF)

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

Summary

ID

NL-OMON57406

Source
ToetsingOnline

Brief title
TEAM-HF

Condition

- Heart failures

Synonym
congestive heart failure (CHF), Heart failure

Research involving
Human

Sponsors and support

Primary sponsor: St. Jude Medical
Source(s) of monetary or material Support: Abbott

Intervention

Keyword: Advanced heart failure, Left Ventricular Assist Devices (LVADs), Mechanical circulatory support (MCS), Pulmonary artery pressures (PAP)

Outcome measures

Primary outcome

TEAM-HF Randomized Arm:

• Survival at 2 years free of disabling stroke, reoperation to replace the

device, or worsening HF requiring listing for urgent heart transplantation,

temporary/durable mechanical circulatory support, enrollment into hospice, or

dependence on intravenous inotropes.

The powered primary endpoint will be analyzed at 2 years following the

Com-Nougue method. The primary endpoint will be compared between the HM3 Group

(HM3 LVAD) and the Control Group (GDMT) within the Randomized population.

Secondary outcome

TEAM-HF Randomized Arm:

• Survival at 2 years.

• Freedom from MAE at 1-year in the HM3 group

Survival at 2 years will be compared between the HM3 Group and the Control

Group within the Randomized population.

Freedom from MAE at 1-year will be evaluated in the As-Treated HM3 group

against a pre-specified performance goal

TEAM-HF Randomized Arm: There are five other secondary endpoints they will be evaluated at 2-years:

1. Quality of life score assessed with the KCCQ.
2. Six-minute walk distance
3. Hospitalizations for HF and/or Urgent HF Visit
4. Days alive and outside of the hospital
5. All-cause hospitalization

Study description

Background summary

Patients with heart failure (HF) suffer from a high degree of morbidity and mortality. Left ventricular device (LVAD) therapy has become the standard of care for the treatment of advanced HF patients who are deemed to be dependent on continuous intravenous inotropes, extending life expectancy, enhancing overall quality of life, and improving functional capacity. However, use of LVADs in ambulatory, non-inotrope dependent advanced HF population is limited. Persistent pulmonary hypertension (PH) secondary to left ventricular failure has emerged as a predictor of increased mortality risk for patients refractory to maximally tolerated guideline directed medical therapy (GDMT). In these patients, left ventricular failure with refractory PH may represent objective criteria to identify advanced HF requiring heart replacement therapies such as LVAD.

Study objective

The TEAM-HF trial consists of two arms: a Randomized Arm and a Single Arm Registry.

TEAM-HF Randomized Arm:
The objectives of the Randomized Arm are two-fold:

1) Demonstrate improvement in survival when non-inotrope dependent advanced HF patients are treated with the HeartMate 3* left ventricular assist system (LVAS) compared to being managed on medical therapy alone; and
2) To establish disease-state criteria to trigger referral for a HeartMate 3 LVAS.

TEAM-HF Single Arm Registry:
The objective of the Single Arm Registry is to examine, in patients with lower PAP, the impact of delayed HM3 LVAS implantation on survival and adverse events.

Study design

TEAM-HF Randomized Arm:

The TEAM-HF The TEAM-HF Randomized Arm is a prospective, randomized, open-label study of LVAD vs continued GDMT in non-inotrope dependent HF patients with refractory PH. Refractory PH for this study is defined as mPAP >= 30 mmHg and determined utilizing the CardioMEMS HF System to identify patients at elevated risk of mortality. All subjects enrolled will be non-inotrope dependent HF patients who are already implanted with a CardioMEMS PA Sensor OR will be implanted with the CardioMEMS PA Sensor after enrollment.

Patients will be randomized in a 1:1 ratio into one of two groups:
• HM3 Group: HeartMate 3 LVAS
• Control Group: Continued GDMT

For patients already implanted with a CardioMEMS PA Sensor: after screening procedures and signing the Informed Consent Form, subjects will complete baseline assessments. Upon meeting randomization criteria, patients who have received GDMT with optimal doses for at least 30 of the last 90 days will be randomized.

For patients requiring a CardioMEMS PA Sensor implant: randomization will take place after a 3-months period of optimization of GDMT. Patients meeting all inclusion and randomization criteria and no exclusion criteria with refractory PH (mPAP >= 30mmHg) will be randomized.

TEAM-HF Single Arm Registry:

The TEAM-HF Single Arm Registry is a prospective, single-arm, open-label registry of non-inotrope dependent HF patients responsive to GDMT (mPAP < 30 mmHg). All subjects enrolled will be only non-inotrope dependent HF patients who will be implanted after enrollment with the CardioMEMS PA Sensor. Patients with an existing CardioMEMS PA Sensor implant will not be enrolled in the TEAM-HF Single Arm Registry. After screening procedures and signing the Informed Consent Form, subjects will complete baseline assessments. After a

3-month period of optimization of GDMT, patients with a mPAP < 30 mmHg (considered responsive to GDMT) meeting all Single Arm Registry criteria may be enrolled in the TEAM-HF Single Arm Registry.

All investigators involved in the conduct of the clinical investigation will be qualified by education, training, or experience to perform their tasks and this training will be documented appropriately. The study will allow patients within the Control Group and the Single Arm Registry to receive delayed LVAD treatment and all transplant eligible patients will have the option to receive heart transplantation during the study duration. Follow up will continue until subjects complete their 5-years visit even in the event of a patient receives an LVAD or transplant. The expected duration of enrollment is approximately 3 years. The total duration of the clinical investigation is expected to be approximately 8 years

Intervention

Subject is willing and able to be implanted with the HeartMate 3 LVAS if randomized to HM3 group.

HeartMate 3* Left Ventricular Assist System (LVAS)

The HeartMate 3 LVAS includes equipment and materials that together comprise a medical device designed to provide therapeutic benefit to those affected with advanced HF. In service, the LVAS assumes some or all of the workload of the left ventricle, thereby restoring the patient's systemic perfusion while palliating the underlying pathology.

HM3 Indications for Use:
In Europe, the HM3 LVAS is intended to provide long term hemodynamic support in patients with advanced, refractory left ventricular HF. It is intended either for temporary support, such as a bridge to cardiac transplantation (BTT), or as permanent destination therapy (DT) and it is intended for use inside or outside the hospital.

For patients requiring implantation of a CardioMEMS PA sensor, randomization will occur after a 3-month period of GDMT optimization. Patients with refractory PH who meet all inclusion and randomization criteria and no exclusion criteria (mPAP >= 30 mmHg) will be randomized.

The CardioMEMS* HF System

The CardioMEMS HF System provides pulmonary artery hemodynamic data used for the monitoring and management of HF patients. The system measures change in PAP which physicians use to initiate or modify HF treatment.

CardioMEMS HF System Indications for Use: In Europe, the CardioMEMS HF System is indicated for wirelessly measuring and monitoring PAP and heart rate in New York Heart Association (NYHA) Class III HF patients who have been hospitalized for HF in the previous year. The hemodynamic data are used by clinicians for HF management and with the goal of reducing HF hospitalizations.

Study burden and risks

The risks associated with the implantation of CardioMEMS HF system and HeartMate 3 are the same as if they were implanted outside the study.
The times of the visits correspond to the normal checks if you had received these aids outside the study.

There may be some inconveniences with the study tests and procedures.
You may feel tired or out of breath during the walking test (which may not be per standard of care).
When you have an additional blood test, you may feel pain or discomfort or bruise where the blood is drawn.
The subject may be anxious when asked to talk about his/her health and when completing the questionnaires.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion Criteria
1. Subject has provided written informed consent by signing the study Informed Consent Form (ICF) prior to any clinical investigation-related procedure.
2. LVEF <=30% and Cardiac Index < 2.2 L/min/m².
3. Limited functional status as demonstrated by 6MWT < 300 m due to HF related reasons.
4. Subject is NYHA Class IIIB (or NYHA Class IV if already implanted with a CardioMEMS PA Sensor per standard of care). (as per CIP addendum the Netherlands)
5. Subject has >= 1 Heart Failure Hospitalization in the last 12 months.
6. Subject is already implanted with a CardioMEMS PA Sensor OR willing to undergo a CardioMEMS PA Sensor implant.
7. Subject is willing and able to be implanted with the HM3 LVAS if randomized to HM3 Group.

See protocol section 5.3.3 for randomization criteria.

Exclusion criteria

1. Subject is < 18 years of age at the time of informed consent.
2. Any use of inotrope therapy in the last 30 days.
3. Contra-indications to HM3 LVAS or CardioMEMS HF system.
4. Etiology of HF due to or associated with uncorrected thyroid disease, obstructive cardiomyopathy, pericardial disease, amyloidosis, severe valvular heart disease, or restrictive cardiomyopathy.
5. Technical obstacles to LVAD or CardioMEMS implantation which pose an inordinately high surgical risk, in the judgment of the implanter.
6. Existence of ongoing MCS.
7. Presence of mechanical aortic valve that will not be either converted to a bioprosthesis or oversewn at the time of LVAD implant.
8. History of any solid organ transplant.
9. Psychiatric disease/disorder, irreversible cognitive dysfunction or psychosocial issues that are likely to impair compliance with the study protocol and LVAS management.
10. Presence of an active, uncontrolled infection.

11. Complex congenital heart disease.
12. Currently Pregnant or capable of becoming Pregnant and Unwilling to Use Contraception with LVAD.
13. History of pulmonary embolism within 30 days prior to enrollment or history of recurrent (>1 episode) pulmonary embolism and/or deep vein thrombosis.
14. Planned VAD or Bi-VAD support prior to enrollment.
15. Presence of any one of the following risk factors for or indications of severe end organ dysfunction or failure:
a. An INR >= 2.0 not due to anticoagulation therapy
b. An eGFR < 30 mL/min/1.73 m2 and nonresponsive to diuretic therapy or receiving chronic dialysis.
c. Biopsy proven liver cirrhosis.
d. Need for chronic renal replacement therapy.
e. History of severe chronic obstructive pulmonary disease (COPD) defined by Forced Expiratory Volume FEV1 < 30% predicted.
f. History of cerebrovascular disease with significant (> 80%) uncorrected internal carotid stenosis.
g. Significant peripheral vascular disease (PVD) accompanied by rest pain or extremity ulceration.
16. Any condition other than HF that could limit survival to less than 24 months.
17. Participation in any other clinical investigation with an active treatment arm that is likely to confound study results or affect the study outcome.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-12-2024
Enrollment:	40
Type:	Anticipated

Medical products/devices used

Generic name:	HeartMate 3
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-04-2025
Application type:	First submission
Review commission:	METC NedMec

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
ClinicalTrials.gov	NCT06526195
CCMO	NL88074.041.24