HeartMate PHP CE Mark Clinical Investigation

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Assess the safety and performance of the HeartMate PHP in supporting patients who are hemodynamically unstable, or at risk of being hemodynamically unstable, while undergoing percutaneous coronary interventions (PCI).

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON40807

Source
ToetsingOnline

Brief title
HeartMate PHP

Condition

- Coronary artery disorders

Synonym
Coronary sclerosis, high-risk PCI

Research involving
Human

Sponsors and support

Primary sponsor: Thoratec Corporation
Source(s) of monetary or material Support: Thoratec Corporation

Intervention

Keyword: Cardiac assist Device, High risk PCI patient

Outcome measures

Primary outcome

Freedom from hemodynamic compromise during PCI procedure defined as: Mean Arterial Pressure (MAP) not falling below 60mm Hg for more than 10 minutes during the PCI procedure and additional pressor medication is not required.

Primary Safety Endpoint:

Composite of Major Adverse Events (MAE):

* device-related cardiac death,

* new Q wave myocardial infarction,

* surgical intervention due to device complication or malfunction,

* device-related access site complication requiring intervention or device-related limb ischemia,

* cerebral vascular accident (CVA),

* new or worsening aortic valve insufficiency,

* major bleeding complication (BARC 3 or >),

* severe hypotension

Primary Endpoint will be evaluated at:

* Post procedure or at hospital discharge (whichever is longer)

* 30 days post procedure

Secondary outcome

1) Efficacy of hemodynamic support as measured by:

* Maximal decrease in cardiac power output (CPO) from baseline

* Changes in central venous pressure from baseline (CVP)

* Changes in pulmonary artery pressure from baseline (PAP)

* Changes in pulmonary capillary wedge pressure from baseline (PCWP)

* Changes in cardiac output from baseline (CO)

* Changes in cardiac index from baseline (CI)

2) Individual components of the Major Adverse Event Composites

Secondary Endpoints will be evaluated at:

* Post procedure or at hospital discharge (whichever is longer)

* 30 days post procedure

Study description

Background summary

The HeartMate PHP system is a new catheter-based heart pump and console designed to provide hemodynamic left ventricular support
during intraprocedural use to maintain adequate systemic cardiac output. The key feature of the HeartMate PHP is its ability to be
deployed percutaneously via an integrated 12F arterial sheath through a 13F to 14F introducer. The catheter then expands to 24F when it is
deployed into the left ventricle across the aortic valve. This feature is made possible by a collapsible impeller and cannula mechanism,
which is expanded upon deployment by the operator. The HeartMate PHP is designed to provide flow up to 4.25L/min against a pressure of 62mmHg.
This study is designed to demonstrate that the pump is safe in use, and can assist to maintain sufficient circulation. In addition thi study is part of the

procedure to receive a CE-mark for this device.

Study objective

Assess the safety and performance of the HeartMate PHP in supporting patients who are hemodynamically unstable, or at risk of being hemodynamically unstable, while undergoing percutaneous coronary interventions (PCI).

Study design

Prospective, nonrandomized, multi-center, open-label trial

Intervention

The HeartMate PHP system is a catheter-based heart pump and console designed to provide hemodynamic left ventricular support during intraprocedural use to maintain adequate systemic cardiac output. The key feature of the HeartMate PHP is its ability to be deployed percutaneously via an integrated 12F arterial sheath through a 14F introducer. The catheter then expands to 24F when it is deployed into the left ventricle across the aortic valve. This feature is made possible by a collapsible impeller and cannula mechanism, which is expanded upon deployment by the operator. The HeartMate PHP is designed to provide flow of over 4 L/min against a pressure of 60 mmHg.

Data will be collected at baseline, during the PCI procedure, postprocedure, discharge, and at 30 days post device removal. All patients will have a follow-up visit at 30 days post-device removal.

Study burden and risks

The HeartMate PHP has not been approved for commercial distribution by the U.S. Food and Drug Administration (FDA) or any other regulatory agency. Extensive testing has been performed on the device in the laboratory and in animal studies The potential risks associated with HeartMate PHP use are consistent with those in procedures such as diagnostic cardiac angiography and percutaneous coronary interventions. In addition to the potential risks associated with those procedures, use of the HeartMate PHP may result in additional potential risks such as those listed in
Section 16.1 (see protocol) Anticipated Potential Adverse Events.
The HeartMate PHP may provide hemodynamic support during high-risk PCI by increasing output from the left ventricle to the ascending aorta at a rate up to approximately 4 LPM. The potential benefits of hemodynamic support using the HeartMate PHP include reduced or eliminated periods of coronary ischemia, more complete revascularization than would be possible without HeartMate PHP support, and reduction or elimination of intraprocedural complications such as

hypotension.

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

- At least 18 years of age.
- Patient presents with a non-emergent need for complex PCI with:
1) an ejection fraction of <=35% requiring hemodynamic support during the procedure, AND
2) the heart team has determined that the patient is not an optimal surgical candidate, OR the patient elects not to undergo surgery
- Written, signed, and dated informed consent

Exclusion criteria

- Emergent PCI
- ST elevation myocardial infarction within 7 days of procedure
- Cardiac arrest within 7 days of procedure requiring CPR or defibrillation
- Hemodynamic support with the HeartMate PHP post-PCI is anticipated
- Cardiogenic shock (SBP <90 mmHg for >1 hour with either cool clammy skin OR oliguria OR altered sensorium OR cardiac index <2.2 L/min/m2)
- Mural thrombus in the left ventricle
- History of aortic valve replacement
- Documented presence of aortic stenosis (orifice area of 1.5 cm2 or less)
- Moderate to severe aortic insufficiency (echocardiographic assessment of aortic insufficiency graded as 2 or higher)
- Severe peripheral vascular disease
- Abnormalities of the aorta that would preclude surgery, including aneurysms and significant tortuosity or calcifications
- Planned use of rotablator or atherectomy during the procedure
- Serum creatinine > 3.5mg/dL within 7 days of procedure
- Liver dysfunction with elevation of liver enzymes and bilirubin levels to >= 3x ULN or INR (Internationalized Normalized Ratio) >= 2
- Uncorrectable abnormal coagulation parameters
- Active systemic infection requiring treatment with antibiotics
- Clinically relevant stroke or TIA within 3 months of procedure. Patients with suspected stroke or TIA within 3 months of procedure must have documented absence of neurological infarction
- Uncontrollable allergy or intolerance to heparin, aspirin, clopidogrel, ionic and nonionic contrast media, or any other potentially required anticoagulants or antiplatelet therapy drugs
- History of heparin induced thrombocytopenia.
- Patient is pregnant or planning to become pregnant during the study period
- Participation in another clinical study of an investigational drug or device that has not met its primary endpoint

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2015
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	Cardiac assist device
Registration:	No

Ethics review

Approved WMO

Date:	03-09-2014
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	NL48976.078.14