St. Jude Medical HeartMate® PHP CE Mark Post Approval Study

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To assess real world experience with HeartMate PHP post CE Mark approval in supporting patients who are hemodynamically unstable, or at risk of being hemodynamically unstable, while undergoing complex percutaneous coronary interventions (PCI).

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON42831

Source
ToetsingOnline

Brief title
PHP PAS

Condition

- Coronary artery disorders

Synonym
stent placement; procedure of heart arteries

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Heartmate PHP, PCI, post-approval, real world experience

Outcome measures

Primary outcome

Primary Performance Evaluation:

Safety Endpoints: Outcomes and Adverse Events

* Death (including cardiac Death)

* 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 5)

Performance endpoints:

* Change in Mean Arterial Pressure from baseline (MAP

* 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)

Secondary outcome

not applicable

Study description

Background summary

Percutaneous Coronary Intervention (PCI) has provided a significantly less invasive alternative than traditional cardiothoracic surgery to treat patients with severe coronary artery disease. A subset of patients undergoing PCI may require the use of hemodynamic support devices such as intra-aortic balloon pumps (IABP) or percutaneous left ventricular support devices in cases of complex coronary anatomy or depressed left ventricular function as a result of acute myocardial infarction and/or cardiogenic shock. These patients are at risk of hemodynamic collapse during PCI due to decreases in coronary perfusion during balloon inflations or in the event of complications such as vessel occlusion or dissection. With advances in PCI technology and improvement in PCI outcomes, an increasing number of patients with severe coronary disease and comorbidities are undergoing PCI.

The need for devices that are able to provide better hemodynamic support than that allowed by the IABP resulted in the development of percutaneous support devices. Over 200 cases of percutaneous support devices have been reported in literature to treat patient in cardiogenic shock, acute myocardiol infarction and those undergoing high-risk PCI. Many of these publications have demostrated the safe use and efficacy of this percutaneously placed devices.

In 2014 a CE mark clinical trial evaluating the use of the HeartMate PHP device in patients with reduced left ventricular function who were at risk of hemodynamic compromise while undergoing high-risk PCI was conducted. The device received CE mark approval in EU. A total of 50 patients were enrolled in this trial in 7 sites. Cardiac output and cardiac index were improved or mantained throughout all cases during the PCI procedure, and all other hemodynamic parameters were stable throughout all procedures.

The purpose of this post approval study is to evaluate the real world use of HeartMate PHP device to support patients at risk of hemodynamic compromise while undergoing complex PCI as a commitment to the CE Mark approval in the EU. The data collection will be similar to the CE Mark study for ease of comparison to the pre-market results and to continue to build a more robust HeartMate PHP

data set in patients undergoing complex PCI.

Study objective

To assess real world experience with HeartMate PHP post CE Mark approval in supporting patients who are hemodynamically unstable, or at risk of being hemodynamically unstable, while undergoing complex percutaneous coronary interventions (PCI).

Study design

Prospective, nonrandomized, multi-center, open-label, post approval trial.

Data will be collected at baseline, during the PCI procedure, discharge, and at 30 days post device removal.

Intervention

use of PHP device during elective high risk PCI

Study burden and risks

The HeartMate PHP has received CE Mark approval for use in high-risk PCI in Europe Extensive testing has been performed on the device in the laboratory and in animal studies. The decision of the use of HeartmatePHP during the high risk PCI is taken by the interventional cardiologist before the PCI procedure. Participation in the study exposures the patient to potential extra risk due to additional measurements by a right heart catheterization. This PCI procedure will thereby potentially be extended by 30 minutes.

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 and in the opinion of the investigator is a risk of hemodynamic compromise during PCI.
* 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 1.5cm2 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
*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

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2016
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Heartmate PHP
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-01-2017
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	NL57557.078.16