IMPella versus IABP REduces mortality in STEMI patients treated with primary PCI IN SEVERE and deep cardiogenic SHOCK. An international multicenter, randomized trial of the Impella cVAD (left ventricular assist) device versus Intra Aortic Balloon Counter Pulsation (IABP) therapy for acute ST-elevation myocardial infarction patients treated with primary PCI in severe and deep cardiogenic shock

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The primary objective of this study is to determine whether the Impella cVAD device vs. IABP therapy leads to a higher 30 day survival rate in shock STEMI patients in the setting of primary PCI.

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

Summary

ID

NL-OMON39892

Source
ToetsingOnline

Brief title
IMPRESS in severe shock

Condition

- Coronary artery disorders
- Decreased and nonspecific blood pressure disorders and shock

Synonym
severe cardiogenic shock, severely depressed heart function

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: residuele research gelden van andere;niet aan dit project gerelateerde bedrijven

Intervention

Keyword: acute ST-elevation myocardial infarction, deep cardiogene shock, percutaneous left ventricular assist device

Outcome measures

Primary outcome

The primary endpoint is 30 day mortality.

Secondary outcome

The secondary endpoints to be compared between the patients treated with

Impella cVAD and IABP :

* Mortality at 6 months, and at 1 to 5 years of follow up

* Composite of death and severe acquired disability after 30 days, 6 months,

and at 1 to 5 years of follow up.

Study description

Background summary

Restoration of antegrade flow in the infarct related coronary artery (reperfusion) is the cornerstone treatment of acute ST segment elevation myocardial infarction (STEMI). Reperfusion therapy reduces myocardial damage and therefore mortality. Cardiogenic Shock STEMI patients treated with primary PCI still have a high mortality despite adequate reperfusion and intra aortic counter pulsation therapy (IABP).
Mechanical support of the left ventricle provides may increase survival of the patients. The IABP offers 'passive' support; its function is dependant on left ventricular function. The Impella cVAD provides active support, by pumping blood from the left ventricle into the ascending aorta, thereby unloading the left ventricle. This may reduce infarct size and improve survival.

Study objective

The primary objective of this study is to determine whether the Impella cVAD device vs. IABP therapy leads to a higher 30 day survival rate in shock STEMI patients in the setting of primary PCI.

Study design

An international multicenter, prospective, randomized, two-arm, open label trial.

Intervention

After primary PCI, patients will be randomized to supportive treatment with either IABP ('routine care') or the Impella cVAD.

Study burden and risks

Patients randomized to treatment with the Impella cVAD are at risk of damage of the bloodvessel wall, through which the Impella is inserted. This may result in a deficiency of blood supply to the involved leg. However, we believe that the potential benefits offset the possible risks. STEMI patients with cardiogenic shock represent a patient population at high risk for mortality, despite revascularization with primary PCI and support with IABP. Treatment with the Impella cVAD may reduce mortality in such patients.

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

1 Delay between onset of chest pain and PCI * 72 hours
2 Cardiogenic shock defined as: systolic blood pressure * 90 mmHg for > 30 minutes or the need for supportive measures to maintain a systolic blood pressure * 90 mmHg.
3 In order to ensure the most extremist category of cardiogenic shock, only patients who are already mechanically ventilated will be enrolled. For this trial we target a patient population with a Ph <7.3 and or lactate levels of around 6 mmol/L.

Exclusion criteria

1 Severe aorta-iliac arterial disease impeding placement of either devices
2 Known severe cardiac aortic valvular disease
3 Serious known concomitant disease with a life expectancy of less than one year

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-06-2012
Enrollment:	43
Type:	Actual

Medical products/devices used

Generic name:	Impella cVAD
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	17-11-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-11-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-01-2014
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	NL37515.018.11