# IMPRESS in Severe Shock.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON24829

**Source**
NTR

**Brief title**
IMPRESS in Severe Shock

**Health condition**

acute myocardial infarction
cardiogenic shock

### Sponsors and support

**Primary sponsor:** Academic Medical Center, Departement of Cardiology

### Intervention

### Outcome measures

#### Primary outcome

30-day mortality rate.

#### Secondary outcome

1. Mortality after 6 months, and at 1 to 5 years of follow up;

2. Composite of death and severe acquired disability after 6 months, and at 1 to 5 years of

follow up.

# Study description

**Background summary**

Background:

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).

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:

All severe shock STEMI patients are randomized to either treatment with the IMPELLA cVAD or with IABP device. Sample size: 48 (24 in each arm). A sample-size re-evaluation takes place when the 30-day outcomes of the first 2 x 16 patients are available.

Main study parameters/endpoints:

The primary endpoint is 30 day mortality rate. The secondary endpoints are mortality after 6 months, and at 1 to 5 years of follow up and a composite of death and severe acquired disability after 6 months, and at 1 to 5 years of follow up. Descriptive endpoints are: The need for and duration of mechanical ventilation and inotropic therapy, renal failure requiring dialysis, duration of hospitalization, the occurrence of severe vascular events, stroke, hemolysis, myocardial (re)infarction, surgery, repeat CAG and repeat PCI, the change in left ventricular ejection fraction (LVEF) en the functional class according to the NYHA-classification and hospital admission after discharge.

**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**

1. During the hospital stay;

2. 30 days;

3. 6 months;

4. 1,2,3,4,5 year.

**Intervention**

Patients in cardiogenic shock after ST-elevation myocardial infarction, treated by primary PCI, are randomized to either treatment with the Impella cVAD device or to standard treatment with IABP (intra-aortic balloon pump).

Both are implanted through the groin. The IABP is a ballon placed in the aorta, which is being inflated during diastole and empties during systole to increase the perfusion of the heartmuscle and decrease the resistance during squeezing. The Impella cVAD is a pump placed over the aortic valve and actively extracts blood from the left ventricle and sprays it in the aorta.

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Delay between onset of chest pain and PCI ≤ 24-72 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.

## Exclusion criteria

1. Severe aorta-iliac arterial disease impeding placement of either devices;

2. Known severe cardiac aortic valvular disease;

3. Known participation in this study or any other trial within the previous 30 days.

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 24-05-2012 |
| Enrollment: | 48 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 24-05-2012 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL3282 |
| NTR-old | NTR3450 |
| Other | METC AMC : 2011_260 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
N/A