IMPRESS in Severe 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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24829

Bron
Nationaal Trial Register

Verkorte titel
IMPRESS in Severe Shock

Aandoening

acute myocardial infarction
cardiogenic shock

Ondersteuning

Primaire sponsor: Academic Medical Center, Departement of Cardiology

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

30-day mortality rate.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

1. During the hospital stay;

2. 30 days;

3. 6 months;

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	24-05-2012

Aantal proefpersonen:	48
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	24-05-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3282
NTR-old	NTR3450
Ander register	METC AMC : 2011_260
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A