IMPRESS in STEMI

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

Samenvatting

ID

NL-OMON27760

Bron
Nationaal Trial Register

Verkorte titel
IMPRESS in STEMI

Aandoening

1. Acute ST-elevation myocardial infarction (Acuut ST-elevatie myocardinfarct);

2. cardiogenic pre-shock (cardiogene pre-shock).

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Efficiacy:
Residual left ventricular ejection fraction, assessed by MRI at 4-month patient follow-up.

Safety:
The primary endpoint is the composite of death, myocardial infarction, target vessel revascularization and stroke (MACCE).

Toelichting onderzoek

Achtergrond van het onderzoek

Background:
Primary angioplasty is currently the optimal reperfusion therapy. Patients with large anterior STEMI have a high risk of developing poor left ventricular (LV) function and a higher mortality. Anterior STEMI patients with heart rate >100/min and/or systolic blood pressure <100 mmHg may qualify as pre-shock patients and are usually treated with IABP, as these patients may benefit from mechanical assistance. However, the currently available and frequently used IABP in these patients has not demonstrated any long-term benefit. The percutaneous Impella may be superior when compared with IABP as it directly unloads the left ventricle, improves coronary circulation and produces a
maximum output of 2,5L/min.

Design:
Multi-center, randomized, prospective two-arm trial with either Impella* or IABP therapy after PCI for acute anterior ST segment elevation myocardial infarction in pre-shock patients. Blinded evaluation of endpoints.

Objective:
The primary objective of this study is to determine whether treatment with Impella compared with IABP therapy after primary PCI reduces infarct size and results in a higher residual left ventricular ejection fraction in acute anterior wall myocardial infarction treated by PCI.

Patients:
130 Patients treated with primary PCI for acute anterior wall STEMI with a heart rate >100/min and/or systolic blood pressure <100 mmHg and clinical signs of pre-shock

Methods:
After oral informed consent has been obtained, the patient is randomized to either treatment with the Impella device or IABP.

Primary efficacy endpoint:
Infarct size after 4 months measured as residual left ventricular ejection fraction (LVEF) assessed by MRI in patients treated with Impella versus IABP.

Secondary efficacy endpoints:
• LV volumes measured by MRI.
• Infarct size measured by MRI.
• Infarct size measured by echocardiography before PCI, before discharge and after 4 months
• Enzymatic infarct size and several other biochemical parameters
• The need for and duration of mechanical ventilation, inotropic therapy or dialysis for renal failure
• Duration of hospitalization and stay at the intensive care and coronary care unit
• The functional class according to the NYHA-Classification at 30 days, 4 months and after 1 year

The primary safety endpoint is the composite of death, myocardial infarction, target vessel revascularization and stroke (MACCE)

The secondary safety endpoint is the occurrence of device failure or malfunction, ventricular arrhythmias, severe vascular events or hemolysis.

Doel van het onderzoek

The primary objective of this study is to determine whether treatment with Impella compared with IABP therapy after primary PCI reduces infarct size and results in a higher residual left ventricular ejection fraction in acute anterior wall myocardial infarction treated by PCI.

Onderzoeksopzet

Data collection takes place before randomization (echocardiography, laboratory measurements),
during hospital stay (laboratory and hemodynamic measurements, etc)
at discharge (laboratory measurements, echocardiography), 30 day telephone follow-up (NYHA class);

4 month follow-up (MRI, echocardiography, lab etc) and 1 year clinical follow-up (lab, NYHA class, etc).

Throughout the study, adverse events and medications are registered.

Onderzoeksproduct en/of interventie

Patients in cardiogenic pre-shock after ST-elevation myocardial infarction, treated by primary

PCI, are randomized to either treatment with the Impella device, a percutaneous left ventricular assist device, to support cardiac pump function; or to standard treatment with IABP (intra-aortic balloon pump), which also has the purpose of supporting the left ventricle.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Delay between onset of chest pain and PCI less than 12 hours;

2. Anterior ST elevation myocardial infarction;

3. A clinical pre-shock state defined as:

a. a heart rate >100/min and/or systolic blood pressure <100 mmHg after PCI procedure;

b. one of the clinical signs of cardiogenic pre-shock, such as cold extremities, cyanosis, oliguria or decreased mental status.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Younger than 30 or older than 75 years of age;

2. Legal incompetence, defined as lacking sufficient capacity to manage the patient¡¯s own affairs or to make or communicate important decisions concerning the patient¡¯s person, family, or property whether the lack of capacity is due to mental illness, mental retardation, epilepsy, cerebral palsy, autism, inebriety, senility, disease, injury, or similar cause or condition;

3. Full blown cardiogenic shock , defined hemodynamically as sustained systolic blood pressure ¡Ü 90 mmHg despite fluid hydration with ¡Ý 2 low dose or 1 high dose vasopressor(s) or inotrope(s) within the last 1 hour. The hemodynamic criteria are a cardiac index of no more than 2.2 liters per minute per square meter of body-surface area and a pulmonary-capillary wedge pressure of at least 15 mmHg if known. Pulmonary-artery catheterization is not required before randomization for patients;

4. Primary PCI at more than 12 hours after the onset of symptoms;

5. Actual primary PCI of the Right Coronary Artery;

6. Thrombolysis within 30 days before admission;

7. Blood transfusion in the previous 24 hours;

8. Tortuous aortic or femoral trajectory;

9. Congenital cardiac and or moderate to severe cardiac valve disease;

10. Mechanical aortic valve prosthesis;

11. Any contraindication for Magnetic Resonance Imaging i.e.:

a. pacemaker;

b. cerebrovascular clips;

c. claustrophobia;

12. Left ventricular thrombus on the echocardiogram after primary PCI;

13. Stroke or transient ischemic attack within the previous 3 months;

14. Known hemoglobin diseases, such as sickle cell or thallasemia;

15. Known infection with human immunodeficiency virus (HIV), hepatitis B virus (HBV), or hepatitis C virus (HCV);

16. Serious known concomitant disease with a life expectancy of less than one year;

17. Chronic use of anti-inflammatory medication, except for the use of NSAID¡¯s (non-steroidal anti-inflammatory drugs);

18. Previous participation in this study or any other trial within the previous 30 days;

19. Current known pregnancy;

20. Circumstances that prevent follow-up (no permanent home or address, transient, etc.)

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-11-2007
Aantal proefpersonen:	130
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-10-2007
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	NL1046
NTR-old	NTR1079
Ander register	: 07/218
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten