IMPRESS in STEMI

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27760

Source
NTR

Brief title
IMPRESS in STEMI

Health condition

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

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

Sponsors and support

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Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

Efficiacy:

1. Differences in infarct size, measured by left ventricular ejection fraction (LVEF) and by contrast enhanced MRI-infarct size as well as differences in LV end-diastolic and end-systolic volumes and remodeling parameters at 4 months;

2. The difference of left ventricular ejection fraction (LVEF) measured by resting echocardiography before randomization (i.e. after primary PCI), before discharge and at 4 months;

3. Implantation delay, defined as the time between randomization and the time point at which the Impella support level is P=2 or the IABP actually starts pumping;

4. Hemodynamic parameters during hospitalization, measured by Swan Ganz catheter;

5. Enzymatic infarct size and several other biochemical parameters;

6. The need for and duration of mechanical ventilation;

7. The need for and duration of inotropic therapy;

8. The need for (temporary) dialysis for renal failure;

9. The need for and duration of hospitalization and stay at the intensive care and coronary care unit;

10. The change and differences in concentrations of NT-proBNP at hospital discharge, at 4 months and after 1 year;

11. The functional class according to the NYHA-Classification, with dyspnea or angina as the limiting factor at 30 days, 4 months and 12 months.

Safety:

The occurrence of device failure or malfunction, ventricular arrhythmias during placement, severe vascular events or hemolysis.

Study description

Background summary

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.

Study 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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.)

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-11-2007
Enrollment:	130
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-10-2007
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	NL1046
NTR-old	NTR1079
Other	: 07/218
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results