Use of IABP to reduce mortality in extensive myocardial infarction with persistent ischemia.

Published: 02-07-2014
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To test if IABP therapy is useful in patients presenting with large acute myocardial infarction complicated by persistent ischemia (no-reflow).

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

Summary

ID

NL-OMON42015

Source
ToetsingOnline

Brief title
IABP in extensive myocardial infarction

Condition

- Myocardial disorders

Synonym
myocardial infarction; heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: contracten met de industrie (Maquet),Maquet

Intervention

Keyword: IABP, myocardial infarction, persistent ischemia

Outcome measures

Primary outcome

Mortality, development of heart failure within six months necessitating

hospital admission, and necessity for mechanical hemodynamic support

Secondary outcome

None.

Study description

Background summary

Patients presenting with large myocardial infarction and poor hemodynamic condition after succesful stenting, have a poor prognosis with respect to outcome and development of heart failure in the future. In some of these patients, IABP is very effective, in others it is not.
Our hypothesis is that in patients in whom persistent ischemia is present (as represented by insufficient ST-segment resolution on the ECG) IABP will be beneficial; whereas in patients with pumpfailure without persistent ischemia, IABP is of little value.

Study objective

To test if IABP therapy is useful in patients presenting with large acute myocardial infarction complicated by persistent ischemia (no-reflow).

Study design

Open randomised pilot study in 100 patients fulfilling the inclusion criteria.

Intervention

Placement of an intra-aortic balloon pump (IABP)

Study burden and risks

There is only a neglectable extra risk or burden for the patients compared with regular treatment.

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

- Age 18 * 80 years old
- Acute ST-segment elevation myocardial infarction with summed ST-segment deviation *15 mm.
- Insufficient ST-segment resolution (<50%) on the ECG made 10-30 minutes after the primary PCI in the catheterization laboratory.

Exclusion criteria

- Initial summed ST-segment deviation less than 15 mm
- ST-segment resolution *50% on the ECG performed in the catheterization laboratory
- Chest pain onset >8 hours before arrival
- Severe aortic valve stenosis/regurgitation
- Aortic abnormalities prohibitive for use of intra aortic balloon pump
- Full blown cardiogenic shock with immediate requirement of left ventricular assist device as judged necessary by the operator
- Inability to provide informed consent
- Pregnancy
- Inability to perform coronary angiography by the femoral approach

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-08-2014
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Intra Aortic Balloon pump (IABP)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-07-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	03-11-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-05-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	10-12-2015
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT02125526
CCMO	NL48245.060.14