A multicenter randomized controlled study of mechanical left ventricular unloading with counterpulsation to reduce infarct size pre PCI for acute myocardial infarction- CRISP-AMI.

Published: 07-12-2009
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To investigate if infarct size can be limited by introduction of IABP prior to intervention.

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

Summary

ID

NL-OMON33290

Source
ToetsingOnline

Brief title
CRISP-AMI

Condition

- Myocardial disorders

Synonym
Acute anterior wall myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Datascope BV

Source(s) of monetary or material Support: De industrie

Intervention

Keyword: Anterior wall myocardial infarction, Infarct size., Intra aortic balloonpumping

Outcome measures

Primary outcome

Infarct size, measured by MRI after 3-5 days.

Secondary outcome

- Left ventricle function + dimensions investigated by MRI and Echo/doppler

parameters

- Resolution of ST-elevation on the ECG

Study description

Background summary

During primary percutaneous coronary intervention (PPCI) for acute myocarial infarction, reperfusion injury may occur.
This injury can be possibly limited by previous introduction of an intra-aortic balloon pump (IABP) prior to PPCI.

Study objective

To investigate if infarct size can be limited by introduction of IABP prior to intervention.

Study design

Randomized controlled multicenter study in 300 patients.

Intervention

Introduction of IABP prior to the PPCI in the patients randomized to IABP.

Study burden and risks

- Controlateral arterial puncture in the patients of the IABP group.
- MRI of the heart after 3-5 days in all patients.

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

Patients between the age of 18-90 years old with an acute anterior wall myocardial infarction and presenting in the hospital within 6 hours of onset of complaints.

Exclusion criteria

- Cardiogenic shock

- previous bypass surgery
- previous myocardial infarction
- known contraindication for MRI

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Intra aortic balloonpump (IABP)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-12-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-01-2010

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
Other	DUHS eIRB registry CR1_Pro00011992
CCMO	NL29245.060.09