Early Beta blocker Administration before reperfusion in patients with ST-Elevation Myocardial Infarction who are planned to undergo primary PCI.

No registrations found.

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

Summary

ID

NL-OMON24992

Source
Nationaal Trial Register

Brief title
Early-ßAMI

Health condition

Acute Myocardioal infarction, rescue PCI, prehospital treatment.
Myocard infarkt
Hartinfarkt

Sponsors and support

Primary sponsor: Maatschap Cardiologie Isala klinieken Zwolle
Source(s) of monetary or material Support: Nederlandse hartstichting

Intervention

Outcome measures

Primary outcome

Infarct size as measured by MRI 1 month post MI.

Secondary outcome

1. Troponin-T after 24 hour of hospitalization

2. Peak CK within hospitalization period

3. Area under CK and CK-MB curve within hospitalization period.

4. Residual ST deviation 1 hr after CAG/PCI

5. Ventricular Fibrillation requiring defibrillation during transportation and hospitalization

6. MACE at 30 days and one year FUP

Safety End Points:

1. The incidence of severe bradycardia, asthma or cardiogenic shock

2. 30 day and one year total mortality

Study description

Background summary

This study evaluates the beneficial effects of early administration of 5 mg intravenous Metoprolol or placebo before reperfusion in the ambulance in patients with ST elevation myocardial infarction.

Study objective

31-3-2014 Hypothesis: Early administration of 5 mg of Metoprolol is associated with a relative 20% reduction in infarct size as measured by cardiac Troponin-T, a total of 408 patients will be enrolled and randomized. Interventions: 5 mg intravenous Metoprolol or matching placebo before reperfusion. Health problems studied: changed "Prehospital treatment" into "Early treatment"

Study design

1. Acute phase;

2. During hospitalization;

3. 30 day's;

4. 1 year.

Intervention

5 mg intravenous Metoprolol or matching placebo before reperfusion in the ambulance.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients ≥ 18 years of age with symptoms of acute ST-elevation myocardial infarction of more than 30 min but less than 12 hours and on the ECG ST-segment elevation of ≥0.1 mV in two adjacent limb electrocardiograph (ECG) leads and ≥0.2 mV in two adjacent precordial ECG leads or new left bundle branch block (LBBB).

2. Verbal followed by written informed consents.

3. PCI-center located within 90 minutes

Exclusion criteria

1. Severe Hypotension (systolic blood pressure < 100 mmHg)

2. Cardiogenic shock (severe dyspnoea, hypotension and oxygen saturation <92%, systolic blood pressure < 100 mmHg and heartrate > 110/min)

3. Known with asthma

4. Severe bradycardia at sinusrythm (< 60 bpm)

5. PR interval >240 ms or second- and/or third degree atrio-ventricular (AV) block

6. History of previous myocardial infarction

7. Killip class III-IV

8. Pacemaker/implantable cardioverter defibrillator (ICD)

9. Unable to provide informed consent

10. Patient is pregnant or breastfeeding

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2010
Enrollment:	408
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	18-10-2010
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	NL2455
NTR-old	NTR2572
Other	EudraCT : 2010-023394-19
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A