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

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

Summary

ID

NL-OMON41647

Source
ToetsingOnline

Brief title
Early-ßAMI

Condition

- Coronary artery disorders

Synonym
heart attack, Myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Maatschap cardiologie Isala

Source(s) of monetary or material Support: Nederlandse hartstichting

Intervention

Keyword: Beta Blocker, PCI, ST-elevation MI

Outcome measures

Primary outcome

Infarct size, as measured by MRI one month after the myocardial infarction.

Secondary outcome

- A single Troponin T measured after 24 hours of hospitalization period

- Peak CK within hospitalisation period

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

- Residual ST deviation 1 hr after CAG/PCI

- Ventricular fibrillation requiring defibrillation during transportation and hospitalisation

- MACE at 30 days and one year FUP

Safety End Points:

- The incidence of severe bradycardia, asthma or cardiogenic shock

- 30 day and one year total mortality

Study description

Background summary

The management of patients with ST elevation myocardial infarction has considerably improved over the past decades, with many factors involved in the reduction of mortality, including early diagnosis and early treatment of the acute event, improved management of complications such as recurrent ischemia

and heart failure, and general availability of pharmacological therapies (1).

Beta-blockers are keystones in the treatment of patients with an acute coronary syndromes. Beta-blockers have indisputably been demonstrated to be clinically useful in the setting of acute myocardial infarction (MI), with a large body of evidence showing mortality reductions when administered early (2-6). Beta-blockers also decrease the incidence of re-infarction, recurrent ischemia, or life-threatening arrhythmias and prevent left ventricular (LV) remodelling (7-9) Therefore, the use of oral beta-blockade constitutes a class I indication in clinical practice guidelines (1). However, whether early intravenous administration of Beta-blockers during the acute phase of MI before reperfusion is effective in not yet clear. Some preclinical studies suggest that beta-blockers decrease the extent of necrosis, (10-12) whereas others have shown no effect (13-15). The results of human clinical studies, mostly performed in or before the thrombolytic era, also are controversial (4,16-19).

A recent study in a swine MI model, a single dose of Metoprolol during ongoing MI, before reperfusion, results in 5-fold-larger salvaged myocardium (27% reduction in MI size). (20).

Therefore, the aim of the current study is to evaluates the beneficial effects of early administration of 5 mg intravenous Metoprolol or placebo before reperfusion in the ambulance/ at the HCK and again 5 mg at hospital admission pre CAG (HCK), in patients with ST elevation myocardial infarction.

Study objective

The primary objective of this randomized trial is to assess the beneficial effects of early administration of 5 mg Metoprolol intravenously before reperfusion on infarct size in patients with ST elevation myocardial infarction who are planned to undergo primary PCI.

Study design

Multi-centre, international, prospective, randomized, double-blind, placebo-controlled trial

Intervention

Only one or two injection of Metoprolol or Placebo. The PCI, blood tests, physical examination and other checks are part of the standard treatment for patients with acute myocardial infarction.

Study burden and risks

The side effects of Metoprolol are: fatigue, dizziness, headache. Low heart

rate and low blood pressure. Nausea, vomiting and abdominal pain are rare.
An MRI scan can do no harm unless patients contain metal objects inside their body. The contrast fluid can cause a warm feeling and in some patients can lead to an allergic reaction.
Other risks are related to the heart attack and the usual treatment for this.

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 >= 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).
• Verbal followed by written informed consents.

• PCI-center located within 90 minutes

Exclusion criteria

• Severe Hypotension (systolic blood pressure < 100 mmHg)
• Cardiogenic shock (severe dyspnoea, hypotension and oxygen saturation <92%, systolic blood pressure < 100 mmHg and heartrate > 110/min)
• Known with asthma
• Severe bradycardia at sinusrythm (< 60 bpm)
• PR interval >240 ms or second- and/or third degree atrio-ventricular (AV) block
• History of previous myocardial infarction
• Killip class III-IV
• Pacemaker/implantable cardioverter defibrillator (ICD)
• Unable to provide informed consent
• Patient is pregnant or breastfeeding

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-02-2012
Enrollment:	450
Type:	Actual

Medical products/devices used

Generic name:	Zotarolimus eluting stent
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	Betaloc IV injection
Generic name:	metoprololtartraat
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	18-01-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-11-2012
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-11-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	22-11-2012
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	28-03-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	18-04-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	16-05-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	12-06-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	01-07-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-11-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-12-2013
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	24-03-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	26-05-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	05-12-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO	

Date:	13-01-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-04-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	08-05-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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
EudraCT	EUCTR2010-023394-19-NL
CCMO	NL34300.075.10