Timing of revascularisation in patients with transient ST segment elevation myocardial infarction

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27736

Source
Nationaal Trial Register

Brief title
TRANSIENT

Health condition

STEMI
NSTEMI
Coronary angiography
Revascularisation
PCI
Transient ST segment elevation myocardial infarction.
Timing

Sponsors and support

Primary sponsor: initiator
Source(s) of monetary or material Support: initiator

Intervention

Outcome measures

Primary outcome

The primary end point of the study is total infarct size as percentage of the left ventricle at baseline CMR scan, performed 4 days after the start of symptoms

Secondary outcome

o The change of gadolinium-enhanced infarct size at 4 months relative to baseline.

o The difference in the area at risk and myocardial salvage between the two treatment groups (immediate versus delayed intervention)

o The difference in microvascular injury between the two treatment groups (immediate versus delayed intervention).

o The change of global and regional myocardial function based on a CMR-segmental analysis (using the 17-segments AHA model) at 4 months relative to baseline at day 3, as measured by CMR.

o The difference in infarct size measured by troponine and CK MB as area under the curve.

o The occurrence of recurrent ischemia requiring urgent revascularisation during the index hospitalisation.

o Occurrence of recurrent symptomatic or asymptomatic ST-segment elevation on continuous 12-lead ECG Holter monitor recording 24 hours after admission and 24 hours after PCI.

o The occurrence within 4 and 12 months of a Major Adverse Cardiac Event (MACE) defined as cardiac death, myocardial infarction, coronary bypass grafting, or a repeat percutaneous intervention of the culprit lesion.

o The presence of clinically overt heart failure at 4 and 12 months.

o The occurrence of bleeding during hospitalisation defined by the TIMI bleeding criteria

Study description

Background summary

Rationale: Patients presenting with ST-elevation myocardial infarction (STEMI), whose symptoms and electrocardiographic changes completely resolve upon admission and before the administration of reperfusion therapy, pose a therapeutic dilemma. The optimal

management of this syndrome, termed as transient STEMI (TSTEMI), has not yet been fully established.
Objective: This study will investigate the optimal timing of coronary angiography and subsequent revascularisation in patients presenting with transient ST elevation myocardial infarction. Comparing coronary angiography and revascularisation immediately or pending on the GRACE score (>140, within 24 hours or <140, within 72 hours)

Study design: The study is a prospective, randomized controlled, multi-centre study.

Study population: The research population will be recruited from the general patient population presenting through LifeNet with ST-segment elevation, and complete normalization of ST-segment elevations on admission at the coronary care unit of the hospital with PCI facilities. A total of 141 consecutive patients will be included.

Intervention (if applicable): The patients will be randomized to either the immediate or delayed coronary angiography and subsequent revascularisation group.
Main study parameters/endpoints: The primary end point of the study is total infarct size as percentage of the left ventricle at baseline CMR scan, performed 4 days after the start of symptoms.

Study objective

We hypothesis that a immediate invasive strategy is superior to an delayed invasive strategy in patients with a transient ST segment elevation myocardial infarction.

Study design

cardiac MRI at 4 days
cardiac MRI at 4 months

Intervention

The patients will be randomized to either the immediate or delayed coronary angiography and subsequent revascularisation group

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Age > 18

- clinical presentation of an acute STEMI including chest pain and ST-segment elevations on the ECG of at least 2 mm in 2 standard limb leads or in 2 contiguous chest leads on the LifeNet ECG.

- complete normalization of ST-segment elevations and resolution of symptoms on the coronary care unit, with or without initial treatment of sublingual nitrate, heparin, P2Y12 inhibitor and/or aspirin.

- analysis in the study requires additionally that the patient can be followed for at least 12 months after the index admission.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:

- previous myocardial infarction
- refractory ischemia, major arrhythmias, hemodynamic instability or heart failure requiring immediate catheterization

- alternative causes of transient ST-segment elevation other than myocardial infarction.
- refusal or inability to give informed consent.

- GFR<30 ml/min.

- other contraindications for MRI

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	140
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40420
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3984
NTR-old	NTR4156
CCMO	NL44982.029.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40420

Study results

Summary results
N/A