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

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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...

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

Summary

ID

NL-OMON40420

Source
ToetsingOnline

Brief title
TRANSIENT trial

Condition

- Coronary artery disorders

Synonym
heart attack, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Myocardial infarction, revascularisation, timing

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

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.

Study 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.

Intervention

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

Study burden and risks

One extra MRI at 4 months (60 minutes)
One extra phone interview at 1 year (15 minutes)

Approximately 5 extra venipunctures with risk of hematoma.

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

- 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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2013
Enrollment:	141
Type:	Actual

Ethics review

Approved WMO Date:	28-10-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-04-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	10-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 27736
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL44982.029.13
OMON	NL-OMON27736