Optimal Timing of Coronary Intervention in Unstable Angina 2.

No registrations found.

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

Summary

ID

NL-OMON26173

Source
Nationaal Trial Register

Brief title
OPTIMA2

Health condition

NSTE-ACS; treatment strategy; Treatment Outcome; Time factors

Non ST hart infarct; Behandel strategie; Behandel uitkomsten; Tijdsfactor

Sponsors and support

Primary sponsor: Cardiology Research Department, Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: fonds = verrichter = sponsor

Intervention

Outcome measures

Primary outcome

Size of MI during initial hospitalization as measured by the AUC of CK-MB.

Secondary outcome

1. Size of MI during initial hospitalization as measured by the AUC of CK-MB for the subpopulation of patients treated with PCI;

2. The composite endpoint of death, MI and unplanned revascularization at 30 days;

3. The composite endpoint of MI and major haemorrhage;

4. Incidence of major haemorrhage up to 30 days;

5. Incidence of minor haemorrhage up to 30 days;

6. Incidence of individual and composite endpoints at 30 days and 6 and 12 months and 5 years including recurrent NSTE-ACS;

7. Any revascularisation and/or restenosis (TVR) up to 6 months;

8. Re-hospitalisation because of coronary artery disease (CAD).

Study description

Background summary

This study is a randomised and prospective open-label multicentre strategy trial in patients admitted with suspected high risk NSTE-ACS.
Approximately 350 patients admitted with NSTE-ACS and coronary anatomy suitable for PCI with stent-implantation will be randomized in a 1:1 fashion.

Informed consent will be obtained from all patients meeting the inclusion criteria before the initiation of any study-specific procedures. After informed consent, patients will be randomized using a computerized algorithm, to urgent PCI or early PCI. All patients will receive swift medical treatment which should be initiated at least 45 minutes before the PCI. The pharmacological therapy advised is pre-medication with a combination of strong, reliable and fast acting platelet inhibitors such as aspirin and a novel P2Y12 inhibitor in combination with a safe anticoagulant. PCI, including adjunctive therapies, will be performed according to standard institutional practices. Stent implantation is mandatory in all patients. All patients will be followed from randomisation through to hospital discharge, with respect to any clinically significant events (death, MI, revascularisation, or major haemorrhage).

Three visits assessing MI (with ECG) and revascularisation procedures will be conducted at 30 days, 6 months and 12 months. The primary endpoint assessments are at the index hospitalization.

Countries of Recruitment: The Netherlands.

Study objective

To evaluate whether an urgent coronary intervention in NSTE-ACS patients, after initiation of state of the art medical therapy, is superior to an early strategy in terms of total myocardial damage measured as the AUC of CK-MB and short and long-terms clinical adverse events.

Study design

During hospitalization:

1. Baseline (T=0): hsTroponin, CK, CK-MB, HS-CRP, NT-proBNP, Hb, Ht, leucocytes, platelets, Na, K, Creatinine, BUN;

2. T= 6,12,24,30,36,42,48: hsTroponin, CK, CK-MB.

Discharge (after at least 48 hr):

At discharge: Troponin, CK, CK-MB, HS-CRP, NT-proBNP, echocardiography.

30 Days Follow Up:

At 30 days: Medical history, ECG, echocardiography.

6 and 12 months and 5 year Follow Up:

At 6 months: Medical history, ECG.

When recurrent ischemia is suspected another blood sample should be obtained to measure: hsTroponin, CK, CK-MB (T= Pain + 0) and at 6 hour intervals after the start of until the CK-MB value has normalized.

Intervention

Diagnostic angiography: When to perform PCI:
After informed consent is obtained, the patient will be randomized to urgent or early angiography. During diagnostic angiography a culprit artery should be appointed if possible and be amenable to PCI with stenting. However, when multiple lesions are present the culprit should be among the lesions to be treated by PCI with stenting. In case of uncertainty, all lesions considered as likely “culprit” lesions should be treated with PCI and stent-implantation. The treatment strategy when multiple (non-culprit) lesions are present is at the

discretion of the operator, whether it is complete or incomplete.

In the following cases PCI should not be performed:
Angiography not demonstrating significant coronary narrowing (no more than 50% by visual assessment in 3 orthogonal views of LCA, 2 of RCA). Patients to be treated by cardiac surgery in the opinion of the treating physician.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age > 21 years;

2. Typical chest pain for angina pectoris lasting at least 10 minutes, within the last 24 hours;

3. No contra-indication to PCI;

4. And at least one of the following criteria:

A. 1 mm of horizontal or downsloping ST depression;

B. Dynamic ST- or T- wave changes > 1 mm in two contiguous leads;

C. Elevated hs troponin (>1xULN);

D. Known coronary artery disease;

E. Two of following risk factors: DM, known hypertension, current smoking, family history for ischemic heart disease, hypercholesterolemia, peripheral artery disease, age over 60 years.

Exclusion criteria

1. Acute ST myocardial infarction;

2. Refractory angina;

3. Severe heart failure;

4. Life-threatening ventricular arrhythmias;

5. Haemodynamic instability;

6. Contraindication for the use of a P2Y12 platelet receptor inhibitor;

7. Participation in another study;

8. Use of oral anticoagulants;

9. Patient is not capable of making a rational decision whether to participate, as is judged by investigators discretion.

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):	01-03-2013
Enrollment:	350

Type:	Anticipated

Ethics review

Positive opinion

Date:	16-02-2013
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	NL3691
NTR-old	NTR3861
Other	MEC : R12.032
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A