

Optimal timing of coronary intervention in unstable angina

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/05/2009	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
A randomised clinical trial examining the outcome of immediate versus early (24 to 48 hours) percutaneous coronary intervention in patients with an acute coronary syndrome without persistent ST-segment elevation

Acronym

OPTIMA

Study objectives

Immediate percutaneous coronary intervention (PCI) in patients with non-ST elevation acute coronary syndrome (NSTEMI-ACS) is superior to early PCI with respect to 30-day size and occurrence of (non-ST-E) myocardial infarction, death and revascularisation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised active-controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Non ST-Elevation Acute Coronary Syndrome (NSTEMI-ACS)

Interventions

Patients admitted with NSTEMI-ACS who are eligible for PCI with stent implantation (as noted after angiography) will be randomised into one of the following treatment arms in this trial:

1. Immediate PCI
2. Early PCI (less than 48 hours after admission, but after 24 hours)

All patients will receive drug eluting stents and platelet IIb/IIIa blockers to at least 12 hours after PCI is administered.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Composite incidence of death, MI and revascularisation up to 30 days post-enrolment.

Key secondary outcome(s)

1. Size of MI during initial hospitalisation, quantified as peak CK-MB (mass), cumulative positive CK-MBs
2. Six month angiographic restenosis as a composite endpoint with MI and death
3. Incidence of individual and composite endpoints at 30 days and 6 and 12 months including recurrent NSTEMI-ACS
4. Any revascularisation and/or restenosis (TVR) up to 6 months
5. Re-hospitalisation because of coronary artery disease (CAD)

6. Incidence of major haemorrhage up to 30 days
7. Hospital costs

Completion date

01/01/2008

Eligibility

Key inclusion criteria

1. Aged greater than 21 years
2. Typical chest pain for angina pectoris lasting at least 10 minutes, within last 6 hours
3. No contra-indication to PCI

And at least one of the following criteria:

4. 1 mm of horizontal or downsloping ST depression
5. Dynamic ST- or T-wave changes greater than 1 mm in two contiguous leads
6. Elevated troponin or creatine kinase myocardial bands (CK-MB)
7. Known coronary artery disease
8. Two of following risk factors: diabetes mellitus (DM), known hypertension, current smoking, family hx, hypercholesterolaemia, peripheral artery disease, age over 60 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Chest pain suspected not to be caused by coronary artery disease (CAD)
2. Acute myocardial infarction requiring reperfusion therapy
3. Thrombolytic therapy less than 24 hours/indication for thrombolytic therapy
4. Recent PCI (less than 14 days)
5. Thrombopaenia (less than $100 \times 10^{12}/\text{mm}^3$)
6. Severe bleeding less than 6 weeks
7. Major surgery less than 6 weeks
8. Cerebral haemorrhage in medical history
9. High blood pressure left untreated (diastolic greater than 100 mmHg, systolic greater than 180 mmHg)
10. Life expectancy less than 1 year due to co-morbidity
11. Known intracranial malformation or neoplasm
12. Participation in other study possibly interfering with the endpoints
13. Inability to follow up
14. Culprit lesion is a restenotic lesion

Date of first enrolment

01/01/2004

Date of final enrolment

01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

Onze Lieve Vrouwe Gasthuis

Amsterdam

Netherlands

1090 HM

Sponsor information

Organisation

Amsterdam Department of Interventional Cardiology (ADIC) (Netherlands)

ROR

<https://ror.org/01d02sf11>

Funder(s)

Funder type

Research organisation

Funder Name

Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009		Yes	No