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Optimal timing of coronary intervention in unstable angina

Submission date	Recruitment status	[ ] Prospectively registered
27/01/2006	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/01/2006	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
11/05/2009	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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 (NSTE-ACS) is superior to early PCI with respect to 30-day size and occurrence of (non-STE) 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Non ST-Elevation Acute Coronary Syndrome (NSTE-ACS)

Interventions
Patients admitted with NSTE-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 measure
Composite incidence of death, MI and revascularisation up to 30 days post-enrolment.

Secondary outcome measures
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 NSTE-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

Overall study start date
01/01/2004

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 kiase 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

Age group
Adult

Sex
Both

Target number of participants
600

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 x 10^12/mm3)
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
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Sponsor information

Organisation
Amsterdam Department of Interventional Cardiology (ADIC) (Netherlands)

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Sponsor type
Research organisation

ROR
https://ror.org/01d02sf11

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Heart Foundation (Nederlandse Hartstichting) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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