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PRoximal Embolic Protection in Acute myocardial infarction and Resolution of ST-Elevation-combined embolic protection and thrombectomy during percutaneous coronary intervention in acute ST-segment elevation myocardial infarction: a randomised comparison using the PROXIS™ device

Submission date 23/01/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/03/2007	**Overall study status** Completed	
Last Edited 26/02/2010	**Condition category** 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

Acronym
PREPARE

Study objectives
The use of the PROXIS™ combined embolic protection and thrombectomy device during primary percutaneous coronary intervention (PCI) leads to a more rapid resolution of ST-segment elevation, to increased thrombolysis in myocardial infarction (TIMI)-graded coronary flow and myocardial blush, to smaller enzymatic infarct-size and is effective in the reduction of distal embolisation compared to standard primary PCI in acute ST-elevation myocardial infarction (MI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the local ethics committee (Medisch Ethische Commissie (MEC), Academisch Medisch Centrum, Universiteit van Amsterdam) on the 15th July 2005 (ref: MEC 05 /168).

Study design
Prospective randomised open trial with blinded evaluation of patient outcomes

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Myocardial infarction

Interventions

Patients with symptoms of acute MI within the previous six hours, persistent ST-elevation and a coronary anatomy suitable for PROXIS™ are randomly assigned to combined embolic protection and thrombectomy with PROXIS™, or standard PCI.

All patients receive:
1. Acetylsalicylic acid (300 mg)
2. Clopidogrel at a starting dose of 600 mg
3. Unfractionated heparin (70 U/kg)

Abciximab can be given at any time of the procedure, at the discretion of the operator.

PCI of the infarct-related artery is performed by experienced operators, according to standard clinical practice, using standard material such as guide-wires, balloons and stents. Serial electrocardiograms (ECGs) are taken prior to, immediately after, 30 minutes, one hour, three and six hours after the final angiogram during the PCI-procedure. Continuous 12-lead ST-segment monitoring is started as early as possible and is continued for at least six hours after the procedure. The continuous ECG is recorded on a study device through routinely placed leads. The continuous ECGs are analysed at the eECG core lab at Duke Clinical Research Institute under the supervision of M. Krucoff.

Angiographic TIMI-graded coronary flow is documented prior to, and immediately after PCI, as well as myocardial blush grade and angiographic signs of distal branch embolisation on the final angiograms after completion of the procedure. Serial creatine kinase myocardial bands (CK-MB) mass, troponin-T, α-hydroxybutyrate dehydrogenase (α-HBDH) and n-terminal prohormone brain natriuretic peptide (NT proBNP) are measured for infarct-size estimation, according to standard clinical procedures.

Clinical follow-up is obtained at one and six months after randomisation and left ventricular function is assessed by magnetic resonance imaging (MRI) between six and nine months. Patients are studied on a clinical 1.5 or 3.0 Tesla scanner with a radio frequency receiver coil.

Functional imaging:
ECG-gated cine steady state free precession (SSFP) magnetic resonance (MR) images are obtained during repeated breath-holds in the three standard long axis views (four-, three- and two-chamber view). Additional short axis slices are acquired covering the entire left ventricle, to examine regional and global left ventricular function.

Infarct imaging:
During intravenous (i.v.) injection of gadopentetic acid (Gd-DTPA) first-pass perfusion imaging is performed with a saturation-recovery gradient-echo pulse sequence. Delayed contrast-enhanced images are acquired 10 and 30 minutes post-contrast with an inversion-recovery gradient-echo pulse sequence to identify the location and extent of myocardial infarction. The data are obtained with slice locations identical to the functional images.

In case of the use of the PROXIS™ combined embolic protection and thrombectomy device, the presence of evacuated material is evaluated by visual assessment and confirmed by pathology. During the study period, baseline data of all not-included patients undergoing primary PCI at our centre are documented.

Intervention Type

Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Acetylsalicylic acid, clopidogrel, abciximab and unfractionated heparin

Primary outcome measure
The primary endpoint of this study is a more than 70% resolution of ST-segment elevation at one hour after PCI, compared to ST-segment elevation immediately prior to PCI.

Secondary outcome measures
The secondary endpoints are:
1. ECG: the time course of the percentage of ST-segment elevation resolution (as a quantitative parameter)
2. Angiographic: the incidence of angiographic evidence distal embolisation based on TIMI-graded coronary flow, myocardial blush grade and distal branch occlusion
3. Laboratory: the myocardial infarct-size as assessed by serial CK-MB mass, troponin-T, α-HBDH, and NT proBNP, according to standard clinical practice
4. MRI: the difference of infarct size measured by left ventricular ejection fraction (LVEF) and by contrast enhanced MRI-infarct size between six and nine months after PCI, between patients treated by standard PCI and patients treated by PCI combined embolic protection and thrombectomy using the PROXIS™
5. Clinical: the incidence of death, MI or rehospitalisation for non-ST-segment elevation acute coronary syndrome (nSTE-ACS), repeat PCI of the infarct related artery, CABG and stroke at one, six and 12 months.

ECG-evaluation for ST-elevation resolution is performed blinded to the randomisation. The TIMI flow rate, the myocardial blush grade and the presence of distal embolisation is assessed on the final angiograms, made immediately following the primary coronary angioplasty, by two experienced investigators who are blinded to all other data.

Overall study start date
05/12/2005

Completion date
01/01/2008

Eligibility

Key inclusion criteria
Consecutive patients with an acute ST-segment elevation MI undergoing primary PCI:
1. Primary PCI within six hours after onset of symptoms of myocardial infarction
2. Electrocardiographic evidence of persistent ST-segment elevation of at least 0.1 mV in two or more contiguous leads at the time of randomisation
3. Proximal obstruction of infarct related coronary artery with TIMI zero to two flow with minimal diameter of 2.5 mm or more
4. The obstruction is amenable to the use of the PROXIS™ as judged by an experienced operator

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
280

Key exclusion criteria
1. Younger than 18 years of age
2. Use of a thrombolytic agent within the previous 48 hours
3. Prior coronary artery bypass graft (CABG)
4. Contraindications to the use of a glycoprotein (GP) IIb/IIIa inhibitor
5. Co-existent condition associated with a limited life expectancy

Date of first enrolment
05/12/2005

Date of final enrolment
01/01/2008

Locations

Countries of recruitment
Canada

Netherlands

Study participating centre
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Sponsor information

Organisation
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Hospital/treatment centre

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http://www.amc.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (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	01/10/2009		Yes	No
Results article	results	01/02/2010		Yes	No