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Randomized comparison of paclitaxel eluting stent versus conventional stent in ST-segment elevation myocardial infarction

Submission date 03/02/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/02/2006	**Overall study status** Completed	
Last Edited 09/05/2011	**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
PASSION

Study objectives
The use of a drug-eluting stent (DES), paclitaxel-eluting stent, in patients undergoing a primary percutaneous coronary intervention (PCI) for acute ST-segment elevation myocardial infarction (STEMI) is safe and may effect short and long term clinical outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
ST-segment elevation myocardial infarction (STEMI)

Interventions
Drug eluting stent (paclitaxel eluting stent) or conventional stent. Follow up planned for year 1, 2, 3, 5 and 10.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Paclitaxel

Primary outcome measure
The primary end point is the composite clinical endpoint of death of all causes, recurrent MI, target vessel revascularization (TVR) or target lesion (within 5 mm of stent edges) revascularization (TLR) at one year.

Secondary outcome measures
1. The composite clinical endpoint of death of all causes, recurrent MI, target vessel revascularization (TVR) or target lesion (within 5 mm of stent edges) revascularization (TLR) at 6 months, 2 and 3 years
2. Occurence of stent thrombosis
3. Success rate of primary PCI

Overall study start date
28/03/2003

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Acute myocardial infarction eligible for primary PCI: >20 min of chest-pain and at least 1 mm ST-elevation in two contiguous leads or a new left bundle branch block
2. Reperfusion expected to be feasible within 6 hours after onset of complaints
3. Stent eligible (coronary at least 2.5 mm) infarct related coronary artery

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
620, recruitment closed

Key exclusion criteria
1. Age >18 and <80 years
2. Reperfusion not achievable within 6 hours of onset of complaints
3. Failed thrombolysis
4. Infarct related artery unsuitable for stent implantation
5. Sub-acute stent thrombosis
6. STEMI caused by in-stent re-stenosis
7. Infarct related vessel/target vessel bypass graft (SVG or LIMA)
8. Contraindication for aspirin and/or clopidogrel: intolerance, allergy
9. Participation in another clinical study, interfering with this protocol

10. Cardiogenic shock prior to randomization
11. Uncertain neurological outcome e.g. resuscitation
12. Intubation/ventilation
13. Known intracranial disease
14. Expected mortality from any cause within the next 6 months

Date of first enrolment
28/03/2003

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) (The Netherlands)

Sponsor details
Onze Lieve Vrouwe Gasthuis
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01d02sf11

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Amsterdam Department of Interventional Cardiology (ADIC)

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	14/09/2006		Yes	No
Results article	results	01/01/2011		Yes	No