

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	<input type="checkbox"/> Prospectively registered
Registration date 03/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 09/05/2011	Condition category Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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. Occurrence of stent thrombosis
3. Success rate of primary PCI

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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
Amsterdam
Netherlands
1090 HM

Sponsor information

Organisation

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

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Amsterdam Department of Interventional Cardiology (ADIC)

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