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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr M.T. Dirksen

Contact details

Onze Lieve Vrouwe Gasthuis Oosterpark 9 Amsterdam Netherlands 1090 HM m.t.dirksen@olvg.nl

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

Kev 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

Amsterdam Netherlands 1090 HM

Sponsor information

Organisation

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

Sponsor details

Onze Lieve Vrouwe Gasthuis P.O. Box 95500 Amsterdam Netherlands 1090 HM

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