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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25456

Source
NTR

Brief title
PASSION

Health condition

PATIENTS UNDERGOING PRIMARY PERCUTANEOUS INTERVENTION FOR ACUTE ST-SEGEMENT MYOCARDIAL INFARCTION.

Sponsors and support

Primary sponsor: Amsterdam Department of Interventional Cardiology (ADIC)

Intervention

Outcome measures

Primary outcome

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

The secondary end points are:
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 year;
2. Occurence of stent thrombosis;
3. Success rate of primary PCI.

Study description

Background summary

To determine the potential benefit of drug-eluting stents in the setting of ST-segment elevation myocardial infarction (STEMI) we will compare the clincial outcomes at 1 year in patients randomized to either drug eluting or conventional stent-implantation. This trial will determine whether the use of a drug eluting stent (paclitaxel eluting stent) in the setting of stemi is safe and improves clinical outcome at 1 year (as an indicator of re-stenosis) compared to conventional stent implantation. This is one of the first randomized, placebo controlled trial to evaluate the beneficial effects of a drug eluting stent in primary percutaneous coronary intervention for acute stemi conducted in a ‘real world’ study population.

Study objective

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.

Intervention

Drug eluting stent (paclitaxel eluting stent) or conventional stent.

Contacts

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Eligibility criteria

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.

Exclusion criteria

1. Age > 18 and < 80 years;
2. Reperfusion not achievable with 6 hrs after 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2003
Enrollment:	620
Type:	Actual

Ethics review

Positive opinion

Date:	26-11-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL496
NTR-old	NTR538
Other	: N/A
ISRCTN	ISRCTN65027270

Study results

Summary results
N/A