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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25456

Bron
Nationaal Trial Register

Verkorte titel
PASSION

Aandoening

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

Ondersteuning

Primaire sponsor: Amsterdam Department of Interventional Cardiology (ADIC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	28-03-2003
Aantal proefpersonen:	620
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	26-11-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A