Optimal Timing of Coronary Intervention in Unstable Angina.

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Immediate PCI in patients with NSTE-ACS is superior to early PCI with respect to 30-day size and occurrence of (non STE) myocardial infarction, death and revascularization.

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

Samenvatting

ID

NL-OMON22720

Bron
NTR

Verkorte titel
OPTIMA

Aandoening

NSTE-ACS

Ondersteuning

Overige ondersteuning: Netherlands Heart Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Composite incidence of death, MI and revascularization up to 30 days post enrolment.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is a randomised and prospective open-label multicenter trial in patients admitted with NSTE-ACS eligible for PCI.
Approximately 600 patients admitted with NSTE-ACS and coronary anatomy suitable for PCI with stent-implantation will be randomized.
Informed consent will be obtained from all patients meeting the inclusion criteria before the initiation of any study-specific procedures. After informed consent, coronary angiography will be performed directly after presentation to assess suitable coronary anatomy for PCI with stent implantation of the lesion/lesions that attributed to the presentation (culprit lesion). When found suitable, patients will be randomized using a computerized algorithm, to immediate PCI or early PCI. All patients will receive an infusion of platelet IIb/IIIa inhibitors during PCI until 12 hours after the procedure. PCI, including adjunctive therapies, will be performed according to standard institutional practices. Stent implantation is mandatory in all patients.
All patients will be followed from randomisation through to hospital discharge, with respect to any clinically significant events (death, MI, revascularisation, or major haemorrhage). Three visits assessing MI (with ECG) and revascularisation procedures will be conducted at 30 days, 6 months and 12 months. The primary endpoint assessments are at 30 days. The total expected duration of a patient’s participation in this trial is approximately 12 months.

Doel van het onderzoek

Immediate PCI in patients with NSTE-ACS is superior to early PCI with respect to 30-day size and occurrence of (non STE) myocardial infarction, death and revascularization.

Onderzoeksproduct en/of interventie

Patients admitted with NSTE-ACS who are eligible for PCI with stent implantation (as noted after angiography) will be randomised into one of the following treatment arms in this trial:

1. Immediate PCI;
2. Early PCI (<48 hours after admission, but after 24 hours).

All patients will receive drug eluting stents and platelet IIb/IIIa blockers to at least 12 hours after PCI will be administered.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age > 21 years;
2. Typical chest pain for angina pectoris lasting at least 10 minutes, within last 6 hours;
3. No contra-indication to PCI;

And at least one of the following criteria:
1. 1 mm of horizontal or downsloping ST depression;
2. Dynamic ST- or T- wave changes > 1 mm in two contiguous leads;
3. Elevated troponin or CK-Mb;
4. Known coronary artery disease;
5. Two of following risk factors: DM, known hypertension, current smoking, family hx, hypercholesterolaemia, peripheral artery disease, age over 60 years.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Chest pain suspected not to be caused by CAD;
2. Acute myocardial infarction requiring reperfusion therapy;
3. Thrombolytic therapy <24 hours / indication for trombolytic therapy;
4. Recent PCI (<14 days);

5. Thrombopenia (<100*1012/mm3);
6. Severe bleeding < 6 weeks;
7. Major surgery < 6 weeks;
8. Cerebral haemorrhage in medical history;
9. High blood pressure left untreated;(diastolic > 100 mmHg, systolic > 180 mmHg);
10. Life expectancy < 1 year due to co morbidity;
11. Known intracranial malformation or -neoplasm;
12. Participation in other study possibly interfering with the endpoints;
13. Inability to follow up;
14. Culprit lesion is a restenotic lesion.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2004
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-10-2005
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	NL418
NTR-old	NTR458
Ander register	: N/A
ISRCTN	ISRCTN80874637

Resultaten

Samenvatting resultaten
N/A