STRESSED study.

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To investigate whether a strategy of direct stenting without pre-dilatation is associated with a reduced incidence of restenosis at 9 month follow-up angiography, compared to conventional stenting with pre-dilatation or compared to a strategy of...

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

Samenvatting

ID

NL-OMON25680

Bron
NTR

Verkorte titel
STRESSED

Aandoening

Stable or unstable angina pectoris or a recent (<30 days) myocardial infarction with objective evidence of myocardial ischemia.

Ondersteuning

Primaire sponsor: Dr AWJ van ¡¦t Hof
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary end point is the mean minimal lumen diameter at follow-up angiography.

Toelichting onderzoek

Achtergrond van het onderzoek

Title:

STRESSED study;
direct Stenting To reduce REStenosis in Stent Era with Drug elution.

Background:

Direct stenting (without pre-dilatation) has been shown to be a safe and effective treatment modality in elective patients as well as in patients who undergo angioplasty (PCI) because of unstable angina. Success rates vary from 90-98%. In most studies it has been shown to reduce procedure length, the use of contrast agent and the number of balloons and wires and therefore has been shown to reduce procedure related costs (1-8).

Objective:

To investigate whether a strategy of direct stenting without pre-dilatation is associated with a reduced incidence of restenosis at 9 month follow-up angiography, compared to conventional stenting with pre-dilatation or compared to a strategy of provisional stenting.

Design:

600 patients with stable or unstable angina, who are candidate for a PTCA, will be randomized to direct stenting, provisional stenting or pre delatation.
After 9 month a follow up angiogram will be made. After 24 month a follow-up will be done.

End Points:

Primary

The primary end point, is the so called ¡¥Late Loss¡¦, defined as the difference in minimal lumen diameter between the first and the follow-up angiogram (derived from two orthogonal views (by the quantitative coronary angiography laboratory).

Secondary

1. Clinical procedural success defined as angiographic success without major adverse cardiac events (MACE): death, myocardial infarction, or myocardial revascularization by repeat

angioplasty or coronary bypass surgery.

2. Rate of major adverse clinical events during the 9 and 24-month follow-up period.

Doel van het onderzoek

To investigate whether a strategy of direct stenting without pre-dilatation is associated with a reduced incidence of restenosis at 9 month follow-up angiography, compared to conventional stenting with pre-dilatation or compared to a strategy of provisional stenting.

Onderzoeksproduct en/of interventie

PCI:

Randomisation to Drug Eluted Stenting (DES) without (group Direct), with (group Conventional) balloon predilatation or provisional stenting (group Provisional).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Men and Women less than 85 years of age;

2. Stable or unstable angina pectoris or a recent (<30 days) myocardial infarction with objective evidence of myocardial ischemia;

3. Lesion with > 50% and < 100% diameter stenosis according to the estimate of the investigator;

4. Single American College of Cardiology/American Heart Association (ACC/AHA) task force classification type A, B1 or B2 non-calcified target lesion;

5. No contraindication to inhibition of platelet function with aspirin and ticlopidine or clopidogrel.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Acute ST elevation myocardial infarction;

2. Unstable angina pectoris, classified as Braunwald category IIIB or C;

3. Bifurcation lesions situated with a side branch > 2.0 mm in diameter;

4. Left main coronary artery lesions;

5. Ostial lesions;

6. Left ventricular ejection fraction of <30%;

7. Contra-indication for follow-up angiography (severe peripheral vessel disease, creatine-clearance < 30 ml/min).

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2005
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	04-08-2005
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	NL80
NTR-old	NTR111
Ander register	: N/A
ISRCTN	ISRCTN41213536

Resultaten

Samenvatting resultaten

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