STRESSED study.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25680

Source
NTR

Brief title
STRESSED

Health condition

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

Sponsors and support

Primary sponsor: Dr AWJ van ¡¦t Hof
Isala Klinieken, locatie Weezenlanden
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Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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.

Study description

Background summary

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.

Study 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.

Intervention

PCI:

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2005
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-08-2005
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	NL80
NTR-old	NTR111

Register	ID
Other	: N/A
ISRCTN	ISRCTN41213536

Study results

Summary results

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8. Wilson SH, Berger PB, Mathew V, Bell MR, Garratt KN, Rihal CS, Bresnahan JF, Grill DE, Melby S, Holmes DR Jr. Immediate and late outcomes after direct stent implantation without balloon predilation.. J Am Coll Cardiol 2000 Mar 15;35(4):937-943.
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PW; MAGIC 5L investigators. The influence of stent length on clinical and angiographic outcome in patients undergoing elective stenting for native coronary artery lesions; final results of the Magic 5L Study. Eur Heart J 2001;22:1585-93.
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