MISSION! Intervention Study.

No registrations found.

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

Summary

ID

NL-OMON28145

Source
NTR

Brief title
MISSION! Intervention Study

Health condition

Acute myocardial infarction.

Sponsors and support

Primary sponsor: Leiden University Medical Center
Department of Cardiology
Albinusdreef 2
2300 RC Leiden
Source(s) of monetary or material Support: Dutch Heart Foundation
Guidant Inc

Intervention

Outcome measures

Primary outcome

In-lesion late loss at 9 months.

Secondary outcome

1. MACE (death, myocard infarction, target vessel revascularisation, target lesion revascularisation) at 12 months;

2. Incomplete stent apposition at 9 months;

3. Minimal lumen areat at 9 months;

4. Fractional flow reserve at 9 months.

Study description

Background summary

The MISSION! Intervention Study is a prospective randomized study comparing non-coated, thin strut, cobalt chromium stents (Vision TM) and sirolimus eluting stents (Cypher TM) for the treatment of patients with acute myocardial infarction.
300 patients will be randomized and treated by primary percutaneous coronary intervention with stent implantation. All patients will have angiographic follow-up at 9 months to assess the primary endpoint with Quantitative Coronary Angiography. In all patients, IVUS will be performed post-intervention and at 9 months follow-up to assess acute and late incomplete stent apposition and neointimal volume.
Moreover fractional flow reserve will be measured at 9 months to assess functional stent patency. At 12 months major adverse events will be counted and analysed according to life table methods.
Clinical and angiographic data will be analyzed according to the principle of intention-to-treat and evaluable group analyses. End-point variables will be presented by means of 95% confidence intervals.

Study objective

Thin strut cobalt chromium stents are not inferior in preventing restenosis compared to sirolimus-eluting stents in patients with acute myocardial infarction.

Study design

N/A

Intervention

1. Percutaneous Coronary Intervention;

2. Intravascular Ultrasound;

3. Fractional Flow Reserve.

Contacts

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Eligibility criteria

Inclusion criteria

1. Between 18 and 80 years of age;

2. ECG evidence of an acute myocardial infarction;

3. De novo native culprit lesion;

4. Target vessel with a reference diameter between 2.25 and 3.75 mm;

5. Target lesion lenth <=24 mm;

6. Written informed consent.

Exclusion criteria

1. Rescue PTCA;

2. Start symptoms >9 hours before the procedure;

3. Left main lesion with >=50% diameter stenosis;

4. Triple vessel disease;

5. Involvment of a major side branch;

6. Previous PCI or CABG of the culprit vessel;

7. Renal insufficiency;

8. Unwilling or unable to comply with the study requirements or follow-up evaluations;

9. Contraindication for abciximab;

10. Extensive peripheral vascular disease;

11. Non-cardiac illness with a life expectancy less than 12 months.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2004
Enrollment:	300

Type: Actual

Ethics review

Positive opinion
Date: 13-09-2005

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	NL357
NTR-old	NTR396
Other	: N/A
ISRCTN	ISRCTN62825862

Study results

Summary results
N/A