MISSION! Intervention Study.

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

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

Samenvatting

ID

NL-OMON28145

Bron
NTR

Verkorte titel
MISSION! Intervention Study

Aandoening

Acute myocardial infarction.

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Department of Cardiology
Albinusdreef 2
2300 RC Leiden
Overige ondersteuning: Dutch Heart Foundation
Guidant Inc

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

In-lesion late loss at 9 months.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

1. Percutaneous Coronary Intervention;

2. Intravascular Ultrasound;

3. Fractional Flow Reserve.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-02-2004
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2005
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	NL357
NTR-old	NTR396
Ander register	: N/A
ISRCTN	ISRCTN62825862

Resultaten

Samenvatting resultaten
N/A