

The MISSION! Intervention Study: A Prospective Randomised Controlled Trial to Evaluate the Efficacy of Drug-Eluting Stents versus Bare-Metal Stents for the Treatment of Acute Myocardial Infarction

Submission date 27/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 27/01/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/08/2010	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR396

Study information

Scientific Title

Acronym

MISSION! Intervention Study

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Randomised open label controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute myocardial infarction

Interventions

The MISSION! Intervention Study is a prospective randomised study comparing non-coated, thin strut, cobalt chromium stents (Vision™) and sirolimus eluting stents (Cypher™) for the treatment of patients with acute myocardial infarction.

300 patients will be randomised 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.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

In-lesion late loss at 9 months

Secondary outcome measures

1. MACE (death, myocardial infarction, target vessel revascularisation, target lesion revascularisation) at 12 months
2. Incomplete stent apposition at 9 months
3. Minimal lumen area at 9 months
4. Fractional flow reserve at 9 months

Overall study start date

01/02/2004

Completion date

31/01/2006

Eligibility**Key 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 length \leq 24 mm
6. Written informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Rescue PTCA
2. Start symptoms >9 hours before the procedure
3. Left main lesion with $\geq 50\%$ diameter stenosis
4. Triple vessel disease
5. Involvement 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

Date of first enrolment

01/02/2004

Date of final enrolment

31/01/2006

Locations**Countries of recruitment**

Netherlands

Study participating centre

Leiden University Medical Center

Leiden

Netherlands

2300 RC

Sponsor information**Organisation**

Leiden University Medical Centre, Department of Cardiology (Netherlands)

Sponsor details

P.O. Box 9600
Leiden
Netherlands
2300 RC

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Charity

Funder Name

Dutch Heart Foundation (Nederlandse Hartstichting [NHS]) (Netherlands)

Alternative Name(s)

Heart Foundation

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Netherlands

Funder Name

Guidant Inc. (USA)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2008		Yes	No
Results article	results	01/11/2009		Yes	No