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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

Registration date
27/01/2006

Overall study status
Completed

Last Edited
13/08/2010

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised open label controlled parallel group trial

Study type(s)
Treatment

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(s)
In-lesion late loss at 9 months

Key secondary outcome(s)
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

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 ≤ 24 mm
6. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key 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. 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)

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

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