Comparison of Biolimus Eluted from a Erodable Stent Coating with Bare-metal Stents in Acute ST-elevation Myocardial Infarction & In Vivo 3-Vessel Assessment of Time-Related Changes of Culprit and Non-Culprit Lessions by Grayscale IVUS, IVUS-VH and OCT in Acute Myocardial Infarction.

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To establish superiority of the biolimus-eluting (BiomatrixTM) stent compared with an otherwise identical bare-metal stent (GazelleTM) in acute ST-segment elevation myocardial infarction (STEMI) in terms of the composite endpoint of cardiac death,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON32636

Source
ToetsingOnline

Brief title
Comfortable AMI trial

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
heart attack, ST-elevation myocardial infarctie

Research involving
Human

Sponsors and support

Primary sponsor: Universitatsspital Bern
Source(s) of monetary or material Support: Swiss National Science Foundation

Intervention

Keyword: Drug-eluting stent, Myocardial infarction, Myocardial reperfusion

Outcome measures

Primary outcome

Major adverse cardiac events (MACEs) in the overall population, defined as the composite of cardiac death, target-vessel relates myocardial infarction (Q-wave and Non-Q wave), or ischemia-driven target lesion revascularization within 12 months.

Secondary outcome

* Clinically and non-clinicall indicated target lesion revascularization (TLR) at 30 days, 1, 2 en 5 years

* Clinically and non-clinicall indicated target vessel revascularization (TVR) at 30 days, 1, 2 and 5 years

* All deaths (cardiac and non-cardiac) 30 days, 1, 2 and 5 years

* Myocardial infarction (Q-wave and NQWMI) at 30 days, 1, 2 and 5 years

* Stent thrombosis rate defined, probable, possible and overall stent thrombosis (according to ARC definition) at 30 days, 1, 2 and 5 years

Study description

Background summary

Treatment of STEMI patients with DES is effective but there remain concerns regarding the long-term safety and adverse effects on the adjacent arterial wall. The biolimus-eluting BiomatrixTM stent addresses these issues by incorporating the following modifications:
- The polymer utilized for controlled drug release is biodegradable and is absorbed within 6-9 months.
- The drug is applied solely to the abluminal stent surface.
- Preliminary results from the randomized LEADERS trial show a favorable outcome compared with sirolimus-eluting stents.
While clinical data show a favorable safety and efficacy profile, they require confirmation in a dedicated randomized trial in the subset of patients with STEMI. The present study is therefore designed to compare the safety and efficacy of the biolimus-eluting BiomatrixTM stent with a bare-metal stent of otherwise identical design in a prospective, multi-center, randomized, controlled trial in patients with acute ST-elevation myocardial infarction. To address the issue of late acquired stent apposition and stent strut coverage, an imaging substudy using grayscale IVUS and OCT will be performed.

Study objective

To establish superiority of the biolimus-eluting (BiomatrixTM) stent compared with an otherwise identical bare-metal stent (GazelleTM) in acute ST-segment elevation myocardial infarction (STEMI) in terms of the composite endpoint of cardiac death, target-vessel related myocardial infarction, and target lesion revascularization at 1 year

Study design

This is a prospective, multi-center, randomized, assessor-blind, trial to be conducted at 10 - 15 interventional cardiology sites. A total of 1100 patients will be randomized on a 1:1 basis to either the biolimus-eluting stent with biodegradable polymer (Biomatrix*) or a baremetal stent (Gazelle*) of otherwise identical design. The number of stents is not limited per patient, but it must be consistently implanted according to the assigned treatment allocation. All patients will be followed clinically for up to 5 years after stent implantation.

Intervention

Not applicable

Study burden and risks

Patients will receive the routine treatment provided in our center. As a consequence, the risk of this trial do not exceed the risk of any routine PCI procedure at Medisch Spectrum Twente, because the PCIs in this Study will not deviate in any way from the local clinical routine. We do not participate in the imaging side of the protocol.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age >= 18 years
* Chest pain > 10 min

* Primary PCI within 24 hours of symptom onset
* ST-segment elevation of >= 1mm in >= 2 continuous leads, or (presumably new) left bundle branch block, or true posterior MI with ST depression of >= 1mm in >= 2 continuous anterior leads
* Presence of at least one acute infarct artery stenoses in a native coronary artery from 2.25 to 4.0 mm in diameter that can be coverd with one or multiple stents
* Signed informed consent

Exclusion criteria

* Female of childbearing potential (age < 50 years and last mentruation within the last 12 months), who did not underwent tubal ligation, ovariectomy or hysterectomy
* Known intolerance to aspirin, clopidogrel, heparin, stainless steel, biolimus or contrast material
* Inability to provide informed consent
* Currently participating in another trial before reaching first endpoint
* Mechanical complications of acute myocardial infarction
* Acute myocardial infarction secondary to stent thrombosis
* Planned surgery within 6 months of PCI unless dual antiplatelet therapy is maintained throughout the perisurgical period
* History of bleeding diathesis or known coagulopathy

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2010

Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Drug eluting stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	22-12-2009
Application type:	First submission
Review commission:	METC Twente (Enschede)

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
ClinicalTrials.gov	NCT00962416
CCMO	NL30168.044.09