Paclitaxel-eluting stent versus conventional stent in STE-myocardial infarction; angiographic long-term evaluation;Long-term angiographic follow-up after primary PCI for acute myocardial infarction; paclitaxel-eluting stent versus bare metal stent, as performed in the PASSION trial
A single blinded, randomized, dual center study

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Angiographic follow-up of DES in large patient groups late after primary PCI is currently unavailable. By extending the PASSION protocol, we have the opportunity to have the first angiographic analysis two to four years after primary PCI, both after…

Ethical review	Approved WMO
Status	Pending
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON30693

Source
ToetsingOnline

Brief title
PASSIONATE

Condition

- Coronary artery disorders

Synonym
arteriosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: eigen middelen

Intervention

Keyword: acute myocardial infarction, angiography, comparison of stents, long-term evaluation

Outcome measures

Primary outcome

A comparison of late angiographic parameters according to initial treatment

method, as well as (in a substudy) intravascular ultrasound meaurements.

Secondary outcome

Secondary endpoints include cinical endpoints as major adverse cardiovascular

events and anginal class.

Study description

Background summary

Long-term angiographic results after elective PCI with the use of BMS have shown sustained efficacy several years after placement. This information concerning stent-patency is currently lacking for stents placed during primary PCI.
DES stents reduce the rate of both short-term and long-term in-stent restenosis after elective PCI, compared to bare-metal stents. At present time, only

limited clinical data are available about the long-term implications of these stents.

Study objective

Angiographic follow-up of DES in large patient groups late after primary PCI is currently unavailable. By extending the PASSION protocol, we have the opportunity to have the first angiographic analysis two to four years after primary PCI, both after the placement of BMS as well as DES, in two pre-specified groups with well matching clinical characteristics.

Study design

The original PASSION clinical study is a prospective, randomized, dual center, single blinded study. Patients were treated randomly with Paclitaxel-eluting stent(s) or a bare metal stent. These patients will be contacted to give permission for a one-day admission to one of the two study centers to undergo bicycle ergometry and coronary angiography, and intravascular ultrasound will be performed in a subgroup of patients.

Study burden and risks

Admission on a one-day basis with diagnostic tests (bicycle ergometry, coronary angiography).
Svere cardiovascular complications related to coronary angiography normally occurs in apprximately 0.1%.

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

Treatment of acute myocardial infarction by primary PCI between 2003 and 2004, and included in the PASSION trial (published Sep 14 2006 in the New Engl J Med)

Exclusion criteria

renal insuffiency at risk for contrast nephropathy (creatinin > 130 mmol/L)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-03-2007
Enrollment:	300
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL15804.067.07