

# **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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	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 measurements.

### Secondary outcome

Secondary endpoints include clinical 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**

### **Public**

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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 insufficiency 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