# Drug Eluting Balloon vs conventional balloon predilatation an Open Randomized trial in Acute myocardial infarction.

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Pending |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON27108

**Source**
NTR

**Brief title**
DEBORA

**Health condition**

Acute Myocardial Infarction
PCI
Drug eluting balloon
stent

### Sponsors and support

**Primary sponsor:** Maatschap Cardiologie Isala Klinieken
**Source(s) of monetary or material Support:** Maatschap Cardiologie Isala Klinieken
dr. H. Suryapranata
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## Intervention

## Outcome measures

### Primary outcome

Primary endpoint:

- Late loss at 9 month follow-up by quantitative coronary angiography.

### Secondary outcome

Secondary endpoint:

Major adverse cardiac clinical events (death, re-infarction, target vessel revascularization) at 1, 9 and 12 months after treatment.

# Study description

### Background summary

Although DES for AMI seems to be safe and feasible, the risk of stent thrombosis remains disappointingly high, despite prolonged dual anti-platelet therapy.
Therefore, rapid-stent re-endothelialization, by capturing patient¡¯s own circulating EPC¡¯s may potentially reduce inflammatory, stent thrombosis, and restenosis. It has been shown that the higher the circulatory ECP¡¯s the lower the late loss, whereas high EPC levels have been observed in the setting of AMI. The use of Genous stent after pre-dilatation with Paclitaxel-eluting balloon (to prevent restenosis) seems to be an ideal combination for the treatment of AMI patients.

### Study objective

Safety and efficacy of the Genous Bio-engineered R Stent™ pre-dilated with paclitaxel-eluting balloon (Dior™) versus the Genous Bio-engineered R Stent™ pre-dilated with non drug eluting balloon in Patients undergoing PCI for ST-segment Elevation Myocardial Infarction

### Study design

Start of trial: October 2008

End of randomization: October 2009

Complete 12-month follow-up October 2010

**Intervention**

- Genous™ Bio-engineered R Stent™ + non-DEB
(non-drug eluting balloon)

- Genous™ Bio-engineered R Stent™ + DEB
(drug (Paclitaxel) eluting balloon (Dior™))

# Contacts

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# Eligibility criteria

## Inclusion criteria

1. Males or females > 18 years of age and < 80 years with symptoms of AMI of more than 30 minutes but less than 24 hours

2. ST segment elevation of > 1 mV in 2 adjacent ECG leads, with cumulative ST segment deviation of 6 mm or more

## Exclusion criteria

- Women of child-bearing potential

1. Severe hepatic or renal disease

2. Previous participation in the study

3. Life expectancy of < 1 year

4. Factors making follow-up difficult

5. AMI pre-treated with thrombolysis

6. Patients who have previously received murine therapeutic antibodies and exhibited sensitization through the production of Human Anti-Murine Antibodies (HAMA)

7. Known sensitivity to aspirin, clopidogrel, or coumadin

8. Patients in whom anti-platelet and/or anticoagulant therapy is contraindicated

9. Unable to provide informed consent

ANGIOGRAPHIC EXCLUSION CRITERIA

1. Unprotected left main disease or single remaining vessel

2. Target lesion in a bifurcation with a large side-branch

3. Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent

4. Patients with coronary vessel diameter of < 2.50 mm or > 4.0 mm

5. Patients with lesions located in saphenous vein grafts

6. Patients with diffuse disease or poor flow distal to the target lesions

7. Patients with tortuous vessels in the region of the obstruction or proximal to the lesion

8. Patients treated with drug-eluting stents

9. Patients previously treated with drug-eluting balloon

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Single blinded (masking used) |
| Control: | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 30-03-2009 |
| Enrollment: | 68 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 01-12-2008 |
| Application type: | First submission |

# 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 |
|---|---|
| NTR-new | NL1500 |
| NTR-old | NTR1570 |
| Other | NL24841.075.08 : ABR |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Study results

**Summary results**
N/A