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

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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...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27108

**Bron**
NTR

**Verkorte titel**
DEBORA

**Aandoening**

Acute Myocardial Infarction
PCI
Drug eluting balloon
stent

### Ondersteuning

**Primaire sponsor:** Maatschap Cardiologie Isala Klinieken
**Overige ondersteuning:** Maatschap Cardiologie Isala Klinieken
dr. H. Suryapranata
Groot Wezenland 20
8011 JW Zwolle

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Primary endpoint: <br>
- Late loss at 9 month follow-up by quantitative coronary angiography.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

Start of trial: October 2008

End of randomization: October 2009

Complete 12-month follow-up October 2010

### Onderzoeksproduct en/of interventie

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

- Genous™ Bio-engineered R Stent™ + DEB

(drug (Paclitaxel) eluting balloon (Dior™))

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

## Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Enkelblind |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 30-03-2009 |
| Aantal proefpersonen: | 68 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 01-12-2008 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL1500 |

| Register | ID |
| --- | --- |
| NTR-old | NTR1570 |
| Ander register | NL24841.075.08 : ABR |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Resultaten

**Samenvatting resultaten**
N/A