# Paclitaxel-Eluting PTCA-Balloon in Combination with the CoroflexTM Blue Stent vs the Sirolimus Coated CypherTM Stent in the Treatment of Advanced Coronary Artery Disease Clnical investigational plan, version 18, 16 october 2006.

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**Ethical review** Approved WMO

**Status** Pending

Health condition type Coronary artery disorders

Study type Interventional

# **Summary**

### ID

NL-OMON31372

Source

ToetsingOnline

Brief title PEPCAD III

### **Condition**

Coronary artery disorders

### **Synonym**

Artherosclerotic cornonary artery disease

### Research involving

Human

## **Sponsors and support**

**Primary sponsor:** B. Braun Melsungen AG Vascular Systems

Source(s) of monetary or material Support: B. Braun Melsungen AG Vasular Systems

### Intervention

Keyword: Drug eluting balloon, Drug eluting stent

### **Outcome measures**

### **Primary outcome**

Primary endpoint:

Late lumen loss at 9 months. A deviation of +/- 3 months to the 9

months FU is accepted.

### **Secondary outcome**

Secondary endpoints:

Procedural success

30-day complication rate (by phone)

Percent stenosis at 9 months

Angiographic binary restenosis rate at 9 months

Acute and cumulative MACE rate at 9 months

Cumulative MACE rate after one years

Cumulative MACE rate after three years

Indication for premature follow-up

# **Study description**

### **Background summary**

Background information

The incidence of in-stent restenosis after percutaneous coronary intervention varies

between 5 and 35% after bare metal stenting and is as high as 19% after the implantation of a drug-eluting stent in patients at moderate risk. Restenosis due to

neointimal hyperplasia is a slow process, suggesting that therapeutic local drug administration would need to be prolonged to be beneficial. Stent-based local drug

delivery provides sustained drug release using special release technologies like polymer coating. However, cell culture experiments indicate that even brief contact

between vascular smooth muscle cells and lipophilic taxane compounds can inhibit vascular smooth muscle cell proliferation for a long period. In experiments in swine,

intracoronary delivery of paclitaxel by contrast media or by a drug-coated balloon

catheter was found to result in vascular tissue concentrations capable of producing

antiproliferative effects, thus leading to a significant reduction in neointimal proliferation. In these animal studies, the most pronounced reduction of neointimal

formation was seen with paclitaxel-coated balloon catheters.

### **Study objective**

The aim of the study is to assess the safety and efficacy of the Paclitaxel-eluting SeQuent Please S stent system in the treatment of stenoses in native coronary arteries with nominal stent diameters between \* 2.5 mm and \* 3.5 mm and < 24 mm in length for procedural success and preservation of vessel patency in comparison to the Sirolimus-eluting CypherTM stent.

### Study design

Study Design

The PEPCAD III study is a prospective, randomized, multi-center, two-armed phase-II

study assessing the 30 days, 9 months, and 1 and 3 year outcome of the Paclitaxeleluting

PTCA balloon in combination with the Coroflex BlueTM stent in comparison to

the Sirolimus-eluting CypherTM stent conducted in Europe.

### Intervention

The patients will be randomized to one of the treatment options: group A: paclitaxel eluting PTCA-balloon in combination with the Coroflex BlueTM stent or,

group B:

Sirolimus-eluting CypherTM stent deployment. angiographic follow-up scheduled at 9 months for all patients.

### Study burden and risks

The most burdening will be the heartcatheterization at 9 months, less burdening will be the bloodsampling.

Study risks can be associated with possible side effects of Paclitaxel delivery:

- Allergic or immunological reaction to drugs or to the balloon coating
- Alopecia
- Anaemia
- Blood transfusion
- Gastro-intestinal tract impairment
- Haematological dyscrasia (incl. leukocytopenia, neutropenia, thrombocytopenia)
- Abnormal liver enzyme values
- Histological changes in the vascular wall, incl. inflammation, cell damage, or necrosis
- Myalgia / arthralgia
- Peripheral neuropathy

Side effects yet unknown cannot be ruled out.

# **Contacts**

### **Public**

B. Braun Melsungen AG Vascular Systems

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### Scientific

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# **Trial sites**

### **Listed location countries**

**Netherlands** 

# **Eligibility criteria**

### Age

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

### Inclusion criteria

- \* Patients with stable or unstable angina or documented ischemia due to a significant lesion in a native coronary artery
- \* Patients eligible for coronary revascularization by means of PCI
- \* Intention to treat one lesion with one stent
- \* Patients must be \* 18 years of age
- \* Patients must agree to undergo the 9 months angiographic follow-up
- \* Patients must agree to undergo the 1 and 3 year clinical follow-up
- \* Patient is able to verbally acknowledge an understanding of the associated risks, benefits, and treatment alternatives to therapeutic options of this trial, e.g. balloon angioplasty by means of the Paclitaxel-eluting PTCA-balloon catheter in combination with the Coroflex BlueTM stent or the Sirolimus-eluting CypherTM stent. The patients, by providing informed consent, agree to these risks and benefits as stated in the patient informed consent document.

Inclusion Criteria: Lesion Related

\* Significant stenoses in native coronary arteries with nominal stent diameters between \* 2.5 mm and \* 3.5 mm and < 24 mm in length

### **Exclusion criteria**

- \* Unprotected left main
- \* In stent restenosis
- \* Indication for more than one lesion to treat, even as staged procedure
- \* Intended bifurcational stenting
- \* Patients requiring chronic anticoagulation
- \* SVG and AG
- \* Acute MI (STEMI, NSTEMI)
- \* Cardiogenic shock

- \* Chronical total occlusions
- \* Pregnancy
- \* Patients with stand alone balloon angioplasty, or stent deployment 6 months prior to enrolment into this study

# 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: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-05-2007

Enrollment: 75

Type: Anticipated

# Medical products/devices used

Generic name: Coroflex DEBlue system

Registration: No

# **Ethics review**

Approved WMO

Application type: First submission

Review commission: METC Amsterdam UMC

# **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 NL17172.029.07