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

Sieversufer 8
D-12359 Berlin
DE
Scientific
B. Braun Melsungen AG Vascular Systems

Sieversufer 8
D-12359 Berlin
DE

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