PEPCAD III

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28432

Bron
NTR

Verkorte titel
PEPCAD III

Aandoening

1. Coronary Artery Disease;

2. Drug eluting Balloon;

3. Sirolimus eluting stent;

(NLD: Kransslagader vernauwing(en),
Medicijn afgevende ballen,
Sirolimus afgevende stent).

Ondersteuning

Primaire sponsor: B Braun Melsungen
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary End-Point:
The primary end point is defined by the late lumen loss in treated segment (= stent +/- 5 mm) at 9 months from the procedure.

Toelichting onderzoek

Achtergrond van het onderzoek

Protocol Summary/Synopsis

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 ¡Ý 2.5 mm and ¡Ü 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:

This study is a prospective, randomized, multi-center, two-armed
phase-II study conducted in Europe.
Number of patients 600 patients will be randomly assigned to either one of the treatment groups in the order of 20 to 40 patients per centre and a minimum of 10 procedures per operator.

Selection criteria Patients with stable or selected forms of unstable angina or
documented ischemia due to a significant lesion in a native coronary artery. Vessels may not supply an entirely infarcted
myocardial area.

Primary endpoint:

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

Secondary endpoints:

1. Procedural success;

2. 30-day complication rate (by phone);

3. Percent stenosis at 9 months;

4. Angiographic binary restenosis rate at 9 months;

5. Acute and cumulative MACE rate at 9 months;

6. Cumulative MACE rate after one years;

7. Cumulative MACE rate after three years;

8. Indication for premature follow-up;

9. Scheduled follow-up Clinical and angiographic follow-up scheduled at 9 months for all patients; 1 and 3 year MACE for all patients.

Doel van het onderzoek

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 ¡Ý 2.5 mm and ¡Ü 3.5 mm and < 24 mm in length for procedural success and preservation of vessel patency in comparison to the Sirolimus-eluting CypherTM stent.

Onderzoeksopzet

With an expected enrolment period of six months and with the scheduled Follow-up period 1 of 9 months, Period 1 shall be completed after 15 months. Data evaluation will require one month after data entry and both, the Study Report Period 1 and the manuscript shall be submitted after one year and nine months.

The one year clinical Follow-Up with special emphasis on MACE rates will be performed with the Short Report Period 2 being provided three months thereafter.

The three year clinical follow-up with special emphasis on MACE rates will be performed with the Summary Report concluding the study four months thereafter.

Thus, the overall duration of the study will be estimated in the range of four years from enrolment of the four patient.

Onderzoeksproduct en/of interventie

The patients will be randomized to one of the treatment options;

1. group A: paclitaxeleluting
PTCA-balloon in combination with the Coroflex BlueTM stent;

2. group B: Sirolimus-eluting CypherTM stent deployment.

Diabetes mellitus is expected to have a major impact on the primary endpoint. A stratification for existence or absence of clinically relevant diabetes in both treatment groups will control this confounder. The existence of clinically relevant diabetes for this purpose is defined as either the patient is insulin-dependent or the patient needs to take oral antidiabetics or HbA1c > 7%. One out of the three criteria must be met.

A list of treatment assignments in treatment groups and confounder strata will be generated blockwise per study centre by the study statistician. These lists will be prepared prior to the initiation of the study. Only the study statistician and the study manager will have copies of the master randomization lists. The randomization lists will be imported into the randomization server of the MARVIN system.

During the trial randomization will be performed by the MARVIN system according to the imported randomization lists generated by the study statistician. The investigator has to carry out the randomization for the patient immediately before Investigational Product administration. He has to document several clinical items first, because they are of importance for the check of eligibility of the patient for randomization and for the calculation of the relevant stratum. The MARVIN system determines the random group and the stratum, displays it and asks for confirmation by authorized study personnel. The account ID of the person performing the randomization in MARVIN as well as the corresponding time stamp will automatically be documented. The patient will receive treatment with the Investigational Product, which is dedicated for him according to the information in MARVIN, only.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with stable or unstable angina or documented ischemia due to a significant lesion in a native coronary artery;

2. Patients eligible for coronary revascularization by means of PCI
Intention to treat one lesion with one stent;

3. Patients suitable for coronary revascularization of any sort (balloon angioplasty, device-assisted balloon-angioplasty, or coronary artery bypass grafting);

4. Patients must be ¡Ý 18 years of age;

5. Women of childbearing potential may not be pregnant nor have the desire to becoming pregnant during the first year following the study procedure. Hence, patients will be advised to use an adequate birth control method up to and including 9 months follow-up;

6. Patients who are mentally and linguistically able to understand the aim of the study and to show sufficient compliance in following the study protocol;

7. Patients must agree to undergo the 9 months angiographic follow-up;

8. Patients must agree to undergo the 1 and 3 year clinical follow-up;

9. 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 ¡Ý 2.5 mm and ¡Ü 3.5 mm and < 24 mm in length.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Unprotected left main;

2. In stent restenosis;

3. Indication for more than one lesion to treat, even as staged procedure;

4. Intended bifurcational stenting;

5. Patients requiring chronic anticoagulation
SVG and AG;

6. Acute MI (STEMI, NSTEMI);

7. Cardiogenic shock;

8. Chronical total occlusions;

9. Pregnancy;

10. Patients with stand alone balloon angioplasty, or stent deployment 6 months prior to enrolment into this study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-02-2008
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-01-2008
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	NL1153
NTR-old	NTR1196
Ander register	B Braun Melsungen : METC VUmc 07-129
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

The Sponsor and Investigator shall agree on the final study report. The latter is to be signed by the Investigator and the investigating physicians involved.
It is intended that the results of the study may be published as scientific literature. Results may also be used in submissions to regulatory authorities. The following conditions are to protect commercial confidential materials (patents, etc), not to restrict publication.
All information concerning Products SeQuentTM and Coroflex BlueTM, such as patent applications, formulae, manufacturing processes, basic scientific data, or formulation information supplied to the Investigator by the Sponsor and not previously published is considered confidential and shall remain the sole property of the Sponsor. The Investigator agrees not to use it for other purposes without the Sponsor¡¯s written consent.
It is understood by the Investigator that the Sponsor will use the information developed in this clinical study in connection with the development of Products SeQuentTM and Coroflex BlueTM and therefore may be disclosed as required to other Investigators or any appropriate international Regulatory Authorities. In order to allow for the use of information derived from this clinical study, the Investigator understands that he/she has an obligation to provide the Sponsor with complete test results and all data developed during this study.
Prior to submitting the results of this study for publication or presentation, the Investigator will allow the Sponsor 30 days in which to review and comment upon the publication manuscript. The Sponsor agrees that before he publishes any results of this study, he shall provide the Investigators at least 30 days for full review of the publication manuscript. In accordance with generally recognised principles of scientific collaboration, co-authorship with any Sponsor personnel will be discussed and mutually agreed upon before submission of a manuscript to a publisher.