PIONEER Trial, A Prospective, Multicentre, Single arm, Non-Inferiority Clinical Trial to evaluate safety of Drug Eluting PTCA Balloons and CoCr coronary Stents mounted on a Drug Eluting Balloon

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To evaluate the safety and performance of the Paclitaxel Eluting Balloon Balloon mounted with a Cobalt Chromium stent (DEBS) and Paclitaxel Eluting Balloon (DEB) in patients with de novo coronary artery disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON36492

Source
ToetsingOnline

Brief title
PIONEER Trial

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, stenosis

Research involving

Human

Sponsors and support

Primary sponsor: Blue Medical Devices BV
Source(s) of monetary or material Support: Blue Medical Devices BV

Intervention

Keyword: DEB, DEB STENT, Paclitaxel, PTCA

Outcome measures

Primary outcome

To assess the safety of the Paclitaxel Eluting Balloon (DEB) and Paclitaxel Eluting Balloon stent (DEBS) in patients with de novo coronary artery lesions by composite of Major Adverse Cardiac Event (MACE) rate at 6 months which must be <12%. MACE is defined as cardiac death, MI (Q-wave and non-Q-wave) and clinically driven target lesion revascularization (PCI and CABG)

Secondary outcome

1. Device Success: The ability of the Drug Eluting Balloon (DEB) to be delivered at the target lesion , to be able to dilate and retrieve the system or, the ability of the Drug Eluting Balloon Stent (DEBS) to be delivered at the target lesion, to be able to deploy the stent and retrieve the delivery system.
2. Lesion treatment success is defined as <50% residual stenosis measured by quantitative coronary angiography (QCA.)
3. Procedure success defined as lesion success without the occurrence of MACE during the hospital stay.
4. MACE rate at 1 month and 1 and 2 year follow up. MACE is defined as cardiac death, MI (Q-wave and non-Q wave) and clinically driven target lesion

revascularization (PCI and CABG)

5. Target lesion revascularization (TLR) at 1 and 6 months and 1 and 2 year

follow up.

6. Target vessel revascularization (TVR) at 1 and 6 months and 1 and 2 year

follow up.

7. Late Lumen Loss (LLL) at 6 months follow up

8. Binary in-segment restenosis at 6 months follow up

9. Stent thrombosis up to 2 year follow up

Study description

Background summary

The development of drug eluting stents (DES) have been very successful in reducing the rate of acute re-interventions and repeated revascularization procedures at follow up as compared to simple balloon angioplasty. However, important drawbacks of stents versus balloons remain.
First, flexibility and deliverability of the stent platform might be a limiting factor in successful delivery of the device. Indeed, improvements in the stent design continuously allow for the treatment of more complex lesions.
Second, implantation of stents reduces the flexibility of the vessel and limits the repeatability of the procedure.
Third, although in-stent restenosis rates have already dropped significantly over the last decade, repeated revascularization procedure still occurs. Neointimal hyperplasia is the main factor responsible for this phenomenon. The time course of this event in humans commonly occurs during the first 6 months after deployment. The degree of the in-stent hyperplasia is influenced by procedural and anatomical and physiological factors. Adding neointimal inhibiting medication directly to the stent surface using a coating technique has been largely evaluated in the last decade.
Fourth, since stents are foreign objects, they are prone to create intraluminal thrombosis. Furthermore, addition of neointimal inhibiting drugs on the stents can further limit the re-endothelialization and healing process around the stent surface, increasing the risk of problems related to the occurrence of subacute and late stent thrombosis. This also implies that long-lasting anti-platelet therapy is required to avoid late thrombotic complications.
To overcome the possible problems with long term toxicity of the used drugs on

these DES types, new efforts are made to develop new ways to deliver the drugs on the treated vessel wall, in order to further improve the acute and long term outcomes of percutaneous coronary interventions.
Drug-coated balloons may represent an alternative option for treatment of both de-novo and in-stent restenotic lesions.
In this study the safety and efficacy of the Paclitaxel Eluting Balloon and Paclitaxel Eluting Balloon stent will be evaluated in patients with de-novo lesions in native coronary vessels.

Study objective

To evaluate the safety and performance of the Paclitaxel Eluting Balloon Balloon mounted with a Cobalt Chromium stent (DEBS) and Paclitaxel Eluting Balloon (DEB) in patients with de novo coronary artery disease.

Study design

Prospective, Multicentre, Single arm, Non-Inferiority Clinical Trial

Intervention

Patients are treated by a PTCA procedure where a Paclitaxel Eluting Balloon mounted with a Cobalt Chromium stent (DEBS) and/or Paclitaxel Eluting Balloon (DEB) is used to treat stenotic lesions.
Which device (DEB or DEBS) is used is on the insight of the treating physician.

Study burden and risks

The occurrence of the complications listed in the adverse event section of the protocol may lead to the need for a repeat catheterization and/or percutaneous intervention, myocardial infarction, emergency bypass surgery, or death. Since the Paclitaxel Eluting Balloon or Paclitaxel Eluting Balloon with Stent are investigational devices, all of the risks associated with its usage are not entirely known, but are believed to be similar to those that are associated with current clinical practices using (drug-eluting) balloons and stents to treat the coronary arteries. Treatment may involve some additional risks to the study patient, the natures of which are not known.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patients with stable angina pectoris (Canadian Cardiovascular Society 1, 2 3) or unstable angina pectoris with documented ischemia (CCS 4, Braunwald Class IB-C, IIB-C or IIIB-C), or patients with documented silent ischemia
2. Patients who are eligible for coronary revascularization (percutaneous angioplasty and/or CABG).
3. Patients with up to two de novo lesion in a native coronary artery >50% and <100% stenosis.
4. Reference diameter between 2.0mm and 4.0mm and maximum lesion length of 26mm
5. Patients willing to provide written informed consent prior to participation and willing and able to participate in all follow-up evaluations.

Exclusion criteria

1. Patients under the age of 18 or unable to give informed consent.
2. Women who are pregnant. Women of child bearing potential must have a negative pregnancy test within 7 days prior to enrollment and utilize reliable contraception at a minimum until after the angiographic follow up.
3. Patients who previously participated in this study.

4. Patient is currently participating in an investigational drug or device study that has not completed the primary endpoint or that clinically interferes with the current study endpoints.
5. Life expectancy of less than 12 months or factors making clinical and/or angiographic follow-up difficult (no fixed address, etc.).
6. Patients treated with drug eluting stent(s) in the target vessel less than 12 months prior to the index procedure
7. Patients with a previous stent in the target lesion (in-stent Restenosis)
8. Patients with angiographic evidence of severe calcification of the target lesion.
9. Angiographic evidence of presence of thrombus in the target vessel
10. Patients who intend to have a major surgical intervention within 6 months of enrolment in the study.
11. Patients with recent (<= 48 hours) myocardial infarction.
12. Patients with a contraindication to an emergent coronary bypass surgery.
13. Any individual who may refuse a blood transfusion.
14. Severe renal insufficiency (creatinine > 160 *mol/L or maximum flow declination rate (GFR < 50 ml/min).
15. Patients with intolerance or contraindication to the required medication (heparin, aspirin, clopidogrel and prasugrel, Paclitaxel).
16. Patients with contrast agent hypersensitivity that cannot be adequately pre-medicated.

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2010
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	PTCA Catheter or Coronary Stent system
Registration:	No

Ethics review

Approved WMO Date:	12-05-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	02-08-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-09-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	15-10-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	23-02-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	26-09-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL31913.060.10