6 months Evaluation of the BIOTRONIK CoCr PRO-Kinetic Coronary Stent System in patients with single de Novo lesions in Native Coronary Arteries

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The primary objective of this study is to evaluate safety and efficacy of the BIOTRONIK PRO-Kinetic coronary CoCr-stent in patients with single de novo lesions of native coronary arteries.

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

Summary

ID

NL-OMON30592

Source
ToetsingOnline

Brief title
Multibene study

Condition

- Coronary artery disorders

Synonym
coronary artery disease, Symptomatic ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Biotronik
Source(s) of monetary or material Support: Door opdrachtgever

Intervention

Keyword: effectiveness, PRO-Kinetic, revascularization, safety

Outcome measures

Primary outcome

The primary endpoint is Target Vessel Failure (TVF) at 180 days.

Secondary outcome

The secondary endpoints to be investigated in this trial include:

• MACE (defined as cumulative incidence of total death, all MIs and TVR) at 30

(telephone FU) and 180 days (telephone FU)

• TVR at 180 days (telephone FU), defined as a repeated procedure in the target

vessel, thus including, but not only limited to, TLR.

• In-stent and in-segment restenosisat 180 days (in the angiography subgroup)

• Radiopacity

• Device success

• Procedure success

• Lesion success

Study description

Background summary

Stenting has become the dominant percutaneous coronary intervention.The main benefit of stenting compared with percutaneous coronary balloon angioplasty consists in a significant reduction in the rate of restenosis and thus of repeated interventions. Ongoing changes in the stent design have improved the procedural success rate and short-term lumen gain. Different stent designs have different impact on restenosis as demonstrated by a number of performed studies.
Much efforts and resources are concentrated on strategies aiming at the

prevention of in-stent restenosis. The identification of stent properties that reduce lumen renarrowing may offer a simple, cost-effective, and readily available option against restenosis.
An important issue in stent design is the thickness of stent struts. Angiographic results of different trails showed that strut thickness affects the results of restenosis. The ISAR-STEREO trial compared two stents with similar design but a different strut thickness. One year after stenting, patients who received stents with thinner struts had a considerably lower restenosis rate than those receiving thicker-strut stents. The magnitude of difference in restenosis in the ISAR-STEREO (42% risk reduction with the thin-strut stent) suggests that strut thickness plays a major role in this process, with relevant implications for stent technology.
The ISAR-STEREO-2 trial compared two stents with different design and different strut thickness. The incidence of angiographic restenosis was 17.9% in the thin-strut group and 31.4% in the thick-strut group. (P<0,001). The TVR due to restenosis was required in 12.3% of the thin-strut group and 21.9% of the thick strut group (P=0,002). When two stents with different design are compared, the stent with thinner struts elicits less angiographic and clinical restenosis than the thicker-strut stent.
Cobalt-chromium stents emerged only recently but are progressively replacing conventional stents made of 316 L stainless steel. Cobalt-chromium has the advantage of being stronger than 316 L stainless steel allowing for construction of stents with thinner struts without compromising radial strength. Furthermore, the presence in the alloy of W-atoms with a high ordinal number gives cobalt-chromium stents sufficient radiopacity even with thinner struts. In addition, cobalt-chromium may confer an advantage in thrombosis safety and create less artifacts during MRI examinations than stainless steel.
The Pro-Kinetic coronary stent is covered with a passive coating named PROBIO. PROBIO coating has also been shown to reduce the factors that contribute to restenosis, such as protein activation, platelet activation and endothelialisation. In-vitro data demonstrate a reduction in the proliferation of smooth muscle cells on silicon carbide coated stents by up to 52% when compared to stainless steel stents.
An indication for stenting using the BIOTRONIK PRO-Kinetic BMS platform will only be sought if the BIOTRONIK PRO-Kinetic BMS platform is determined to be non-inferior to the Multi-Link Vision stent from Guidant. Effectiveness and safety of the BIOTRONIK PRO-Kinetic BMS platform for stenting coronary lesions will be determined by Target Vessel Failure (TVF) 6 months after implantation. Non-inferiority to the Guidant Multi-Link Vision Registry Target Vessel Failure using the Multi-Link Vision stent will support the BIOTRONIK labeling for stenting coronary lesions.

Study objective

The primary objective of this study is to evaluate safety and efficacy of the BIOTRONIK PRO-Kinetic coronary CoCr-stent in patients with single de novo

lesions of native coronary arteries.

Study design

The PRO-Kinetic study is a multi-center, prospective, consecutive non-randomized study enrolling 200 patients with single and multiple de novo lesions in native coronary arteries who meet entry criteria. Those who provide informed consent will be enrolled to receive the PRO-Kinetic stent. Telephone follow-up will be performed at 1 month for all enrolled patients. After 6 months 100 patients will have an angiographic follow-up and 100 patients will be checked by telephone again. After 12 months a telephone follow-up will be performed for all enrolled patients.
Patients who underwent treatment of non-target lesions less than 30 days prior to the index procedure, should not be enrolled in this trial.

Intervention

All patients will receive the PRO-Kinetic stent

Study burden and risks

Benefits:
Percutaneous transluminal coronary angioplasty (PTCA) has been widely used as an alternative to medical or surgical treatment in patients with symptomatic coronary artery disease. The principal limitations of PTCA (abrupt closure, intimal dissection, and restenosis) are solved by implantation of coronary stents. The PRO-Kinetic stent system is developed to provide an optimal luminal diameter and maintain arterial patency during and after percutaneous coronary interventions.

Risks related to the implantation of the PRO-Kinetic stent system are supposed to be the same as those associated with other percutaneous treatment procedures for a diseased coronary artery using any other bare metal stent.
The following complications, also related to standard PTCA, coronary angiography, and coronary stenting, could happen:
• Death
• Access site (femoral, radial or brachial) aneurysm, pseudoaneurysm, or arteriovenous fistula
• Requirement for emergency coronary artery bypass graft (CABG)
• Stroke / transient ischemic attack
• Cardiac tamponade
• Dissection, perforation, or rupture of the coronary artery
• Embolism (air, tissue, device [stent], or thrombus)
• Stent thrombosis
• Early or late stent occlusion

• Total occlusion of the artery
• Acute myocardial infarction
• Restenosis of the stented artery
• Arrhythmias
• Hemorrhage, possibly requiring transfusion
• Renal insufficiency
• Respiratory failure
• Shock / pulmonary edema
• Abrupt vessel closure or spasm
• Hypertension / hypotension
• Allergic reaction (to contrast media, antiplatelet therapy, stent material)
• Peripheral ischemia / peripheral nerve injury
• Infection or fever
• Unstable angina, myocardial ischemia
• Pain at catheter insertion site
• Balloon rupture
• Failure to deliver the stent to the intended site of the vessel
• Incomplete stent apposition
• Stent compression
• Hematoma

The occurrence of the complications listed above could lead to the necessity of a repeat percutaneous coronary intervention, or to a myocardial infarction, an emergency coronary artery bypass graft, or even to death. The PRO-Kinetic is a CE approved coronary stent system, so the risks should be similar to those associated with the implantation of any other bare metal stent.

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

Patient must be at least 18 years old
Patients must be eligible for PTCA
Documented stable (Canadian Cardiovascular Society Classification (CCS) 1,2,3 or 4) or unstable (Braunwald type I,II, III and A,B or C) angina pectoris, or documented silent ischemia.
LVEF > 30 % documented within last 6 weeks

Exclusion criteria

Planned treatment with any other PCI device in target vessel except the pre-dilatation balloon
MI within 72 hours prior to the index procedure, or CK > 2 times the local upper limits of normal, measured on the day of the index procedure
Patient is in cardiogenic shock
CVA within last 6 months

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-07-2006
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	CoCr PRO-Kinetic Coronary Stent System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-07-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-02-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	27-03-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-11-2008
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	11-02-2009
Application type:	Amendment

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	30-03-2009
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	NL12696.100.06