The Treatment of Coronary Artery Lesions Using the PRO-Kinetic Energy Cobalt-Chromium, Bare-Metal Stent (BIOHELIX-II)

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The primary objective of this study is to demonstrate the clinical performance of PRO-Kinetic Energy stent in subjects with atherosclerotic disease of native coronary arteries.

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

Summary

ID

NL-OMON39866

Source
ToetsingOnline

Brief title
BIOHELIX-II

Condition

- Coronary artery disorders

Synonym
coronary artery diease, coronary lesions

Research involving
Human

Sponsors and support

Primary sponsor: Biotronik
Source(s) of monetary or material Support: BIOTRONIK AG

Intervention

Keyword: bare metal stent, coronary artery disease, PRO-Kinetic Energy

Outcome measures

Primary outcome

In-stent late lumen loss at 9 months.

Secondary outcome

Event rates will be estimated for the following endpoints at 1, 9 and 12 months

post-index procedure unless otherwise noted:

• Target vessel failure (TVF) rate

• Individual components of the TVF rate (cardiac death, myocardial infarction

(MI), ischemia-driven target vessel revascularization (TVR))

• Overall TVR rate

• TLF rate, including individual components of the target lesion failure (TLF)

rate (cardiac death, myocardial infarction, ischemia-driven TLR)

• Overall TLR rate

• Rate of all cause mortality and all cause MI, including individual components

• Stent thrombosis rate

• Procedure success

• Device success

• Lesion success

• Angina pectoris classification

• Rates for individual adverse events

Study description

Background summary

Percutaneous transluminal coronary angioplasty (PTCA) has historically been used in addition to other treatment modalities in patients with symptomatic coronary artery disease (CAD). However, there are major limitations to using PTCA as a standalone treatment, including the high incidence of intimal dissections, abrupt vessel closure and restenosis. As a result, the standard treatment option for CAD has expanded to include both bare-metal and drug-eluting coronary stents. Early generations of bare-metal stents were constructed of a 316 low-carbon stainless steel; however, newer models utilize CoCr alloys that have proven both stronger and denser than the stainless steel stents. The increase in strength from the CoCr alloys has allowed for thinner struts, thereby affording an increased flexibility and deliverability without compromising radial strength or radiopacity. Recent studies have indicated that the ability of the CoCr alloys to provide thinner struts has yielded less angiographic and clinical restenosis compared to the thicker-strut stainless steel stents. Despite the recent advances in bare-metal technology, drug-eluting stents remain the more common treatment choice for symptomatic CAD due to the advantages in reducing long-term restenosis rates. However, the latest generation of bare-metal stents is closing the gap when comparing target vessel revascularization and bare-metal stents remain an important option for patients unable to follow required dual antiplatelet therapy guidelines post stent implantation and patients likely to undergo invasive surgeries following stent placement. This study will be the first study to evaluate late lumen loss angiographically after 9 months in patients with CAD treated with a CoCr bare metal stent (i.e. PRO-Kinetic Energy) and therefore will provide essential information regarding the use of CoCr bare metal stents.

Study objective

The primary objective of this study is to demonstrate the clinical performance of PRO-Kinetic Energy stent in subjects with atherosclerotic disease of native coronary arteries.

Study design

Prospective, non-randomized, multi-center, study performed in Europe with a minimum of 60 evaluable patients. A total of 80 patients will be enrolled to compensate for a 25% drop-out rate.

Intervention

Potential subjects will undergo CAD screening according to each investigative

site*s standard of care. The medical history of individuals with CAD who qualify for a percutaneous coronary intervention (PCI) procedure will be evaluated and compared to all initial enrollment criteria. Potential subjects must have documented evidence of a positive functional ischemia study (e.g. exercise treadmill test, thallium stress test, SPECT, stress echocardiogram or cardiac CT) or documented evidence of stable or unstable angina pectoris to be considered for the study.

Following confirmation of all initial enrollment criteria including a negative pregnanvy test for child bearing women, potential study subjects will proceed with routine laboratory assessments and a 12-lead electrocardiogram (ECG) according to each site*s standard of care to ensure suitability to undergo a PCI procedure. The testing results will then be compared to the relevant procedure-related eligibility criteria and, if within acceptable limits, the subject will provide written informed consent for enrollment in the study. For any routine, pre-procedure testing that is outside of protocol requirements, subject informed consent will be obtained and these tests performed according to the protocol. Written informed consent may be obtained on the day of the index procedure (prior to any study-related procedures) or within 30 days prior to the index procedure. Subjects whose laboratory values and ECG analysis are acceptable (none within exclusion criteria specifications) will continue to the index procedure for further inclusion and exclusion criteria screening.

Prior to the placement of an investigational stent, a diagnostic angiogram will be performed to characterize the lesion(s) and confirm the procedure-related eligibility criteria. If the diagnostic angiogram reveals that the subject is ineligible for the investigational stent implant based on the study eligibility criteria, the subject will be considered a screen failure and exited from the study. If the diagnostic angiogram confirms the procedure-related eligibility criteria, but the subject experiences a complication from either pre-dilatation of the target lesion or treatment of a non-target lesion (stent does not enter the guide catheter), the subject will be considered a procedure failure and exited from the study. However, if the investigational stent system enters the guide catheter following the diagnostic angiogram, the subject will be considered evaluable for the study endpoint analyses.

A final angiogram will be obtained immediately following the investigational stent placement. Likewise, all evaluable subjects will have cardiac biomarker levels assessed and a 12-lead ECG performed post-index procedure and prior to hospital discharge.

All evaluable subjects will be followed for a total of 12 months post-index procedure. The follow-up schedule will include an intermediate study visit at 1 month and a follow-up angiogram at 9 months to assess the primary endpoint, with a long-term study visit at 12 months. After the final study visit, the subject*s participation in the study is complete. Each subject will be

subsequently followed per the investigative site*s standard of care.

Study burden and risks

The risks associated with this study are identical to the risks that would occur if the subject was to receive the investigational coronary stent and not participate in the study. These risks are listed in the Instructions for Use as this product is a CE-marked product and approved for use in the Netherlands. The patient is subjected to additional risks by performing the follow-up angiogram 9-months after the procedure, but also gains the benefit of an additional diagnostic test that could possibly detect a coronary lesion that requires intervention. In addition, that subject will need to donate a small amount of time for a follow-up at 1 and 12 months after the initial procedure by participating in a telephone interview.

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

For a subject to be enrolled in the study and considered for the index procedure, the following initial inclusion criteria must be met:
• Age * 18 years
• Willingness to comply with study follow-up requirements
• Candidate for a PCI procedure
• Candidate for coronary artery bypass graft surgery
• Documented evidence of stable or unstable angina pectoris or positive functional ischemia study (e.g. exercise treadmill test, thallium stress test, SPECT, stress echocardiogram or cardiac CT)
* Stable angina pectoris is defined as a documented Canadian Cardiovascular Society Classification of I, II, III or IV
* Unstable angina pectoris is defined as a documented Braunwald Classification of B & C, I, II, III
• Written informed consent;For a subject to receive an investigational stent, the following procedure-related criteria must be met:
• De novo or restenotic lesion in a native coronary artery; restenotic lesions must have been previously treated with only standard PTCA (treatment must be > 12 months prior to the index procedure)
• Target lesion must be in a major coronary artery (target vessel). The target vessel includes the entire territory of the left anterior descending artery, left circumflex artery or right coronary artery and any major side branch of the artery.
• Lesions may be one solid lesion or a series of multiple, smaller lesions to be treated as one lesion
• Target lesion must be treatable with a single investigational stent; an additional stent may be used when treating a vessel dissection or another similar intra-procedure complication (use of investigational stent preferred)
• Angiographic evidence of >= 50% and < 100% stenosis (by operator visual estimate) with a TIMI flow > 1
• Target lesion length of <= 31 mm by operator visual estimate
• Target vessel reference diameter of 2.25 mm to 4.0 mm by operator visual estimate

Exclusion criteria

For a subject to be enrolled in the study and considered for the index procedure, the following initial exclusion criteria must not be present:
• Baseline LVEF of < 30%; LVEF may be measured and assessed by standard-of-care echocardiography procedures within 90 days of the index procedure or by a left ventriculogram prior to the index procedure (operator visual assessment)
• PCI in any vessel 30 days prior to the index procedure or planned for within 30 days after the index procedure
• Intolerance to contrast agents that cannot be medically managed and/or intolerance to

antiplatelet, anticoagulant or thrombolytic medications
• Any other medical condition, that in the opinion of the investigator, poses an unacceptable risk for implant of a stent according to the study indications
• Pregnant, planning to become pregnant or nursing during the course of the study. Women of child-bearing potential must have a negative blood pregnancy (beta hCG) test. Female subjects who are surgically sterile or post-menopausal are exempt from having a pregnancy test.
• Known allergy to L-605 CoCr alloy (cobalt, chromium, tungsten and nickel) or amorphous silicon carbide
• Life expectancy of less than one year
• Participation in any other clinical investigational device or drug study. Subjects may be concurrently enrolled in a post-market study, as long as the post-market study device, drug or protocol does not interfere with the investigational treatment or protocol of this study.;For a subject to receive an investigational stent the following procedure-related criteria must not be present:
• Concomitant renal failure with serum creatinine level > 2.5 mg/dL
• Unprotected left main CAD (> 50% diameter stenosis by operator visual estimate)
• Target lesion has been treated with a stent, cutting balloon or atherectomy any time prior to the index procedure or has been treated with PTCA within 12 months prior to the index procedure
• Target vessel treated with brachytherapy anytime prior to index procedure
• Planned PCI in the target vessel within 9 months after the index procedure
• Target vessel has a non-target lesion with a > 50% stenosis that requires treatment during the index procedure and is <15 mm apart from target lesion
• Lesions preventing distal perfusion (TIMI flow 0 and 1) prior to wire crossing
• Target lesion is in the left main coronary artery or within 2 mm of the origin of the left anterior descending artery or left circumflex artery by operator visual estimate
• Target lesion is located within a saphenous vein graft or arterial graft
• Target lesion involves a bifurcation - lesion is located in a major coronary artery and involves a side branch with a diameter > 2 mm (by operator visual estimate)
• Presence of a complication following pre-dilatation of target lesion
• Presence of a complication following treatment of a non-target lesion (if applicable)
• Presence of a target vessel/lesion that has excessive tortuousity/angulation or is severely calcified preventing complete inflation of an angioplasty balloon
• Angiographic evidence of thrombus within the target lesion
• Target lesion is located within an aneurysm or associated with an aneurysm in the vessel segment either proximal or distal to the target lesion
• Use of cutting balloons, atherectomy or ablative devices immediately prior to investigational stent placement

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-08-2013
Enrollment:	27
Type:	Actual

Medical products/devices used

Generic name:	PRO-Kinetc Energy Coronary Stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	12-04-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	25-06-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	12-11-2013
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
ClinicalTrials.gov	NCT01811927
CCMO	NL42602.100.12

Study results

Date completed: 31-10-2014

Actual enrolment: 18

Summary results
Trial is onging in other countries