The treatment of coronary artery lesions using the PRO-Kinetic energy cobalt-chromium, bare-metal stent (BIOHELIX-I)

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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	Interventional

Summary

ID

NL-OMON43820

Source
ToetsingOnline

Brief title
BIOHELIX-I

Condition

- Coronary artery disorders

Synonym
coronary artery disease, 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

The primary endpoint for the study is the TVF rate at 9 months post-index procedure.

The TVF rate includes a composite of cardiac death, MI and TVR. The definition of cardiac death follows the Academic Research Consortium (ARC) recommendation of any death adjudicated by the independent CEC as cardiac in origin.19 All deaths reported during the study will be considered cardiac, unless an unequivocal, non-cardiac cause is indicated on the subject*s death report. Cardiac death will include all deaths related to a cardiac diagnosis, complication of the index procedure, treatment for a complication of the index procedure or an unexplained cause. Likewise, any unexpected death reported during the study of a subject with a co-existing and potentially fatal non-cardiac disease will be classified as cardiac in nature, unless subject history related to the non-cardiac diagnosis suggests death was imminent.

Secondary outcome

Event rates will be estimated for the following endpoints at 1, 9, 12, 24 and 36 months post-index procedure unless otherwise noted:

* TVF rate (primary endpoint at 9 months)

* Individual components of the TVF rate (cardiac death, MI, ischemia-driven TVR)

* Overall TVR rate

* TLF rate, including individual components of the TLF rate (cardiac death, MI,

ischemia-driven TLR)

* Overall TLR rate

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

* Stent thrombosis rate

* Index procedure success

* Device success

* Lesion success

* Angina pectoris classification

* Rates for individual adverse events

Study description

Background summary

Coronary artery disease is a common, but serious condition occurring with the formation of atherosclerotic plaque inside the arteries supplying blood to the heart. The buildup of plaque, or atherosclerosis, is caused by the collection of cholesterol and fat circulating in the blood stream. Over time, atherosclerosis causes a narrowing or blockage of the coronary arteries, thereby preventing oxygen-rich blood from reaching the heart muscle. This can result in symptoms of angina which may manifest as chest pain, shortness of breath or heart attack. Coronary artery disease affects approximately 16 million American adults and is the leading cause of death in the United States among both men and women. , Prevention and treatment of CAD focuses on lifestyle changes, control of modifiable risk factors, medication and percutaneous or surgical revascularization.

Percutaneous transluminal coronary angioplasty (PTCA) has historically been used in addition to other treatment modalities in patients with symptomatic 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.

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, Investigational Device Exemption (IDE) study performed in the United States, Canada and Europe with a minimum of 296 evaluable patients.

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, 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 36 months post-index procedure. The follow-up schedule will include an intermediate study visit at 1 month and a primary endpoint study visit at 9 months, with long-term study visits at 12, 24 and 36 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 medical device in this study (i.e. PRO-Kinetic Energy) is a CE-marked product being used within its approved indication for use. The patient will be treated with the medical device regardless of his/her participation in this study, thus the associated risks are the same if the patient did not participate in the study. Patients will also be asked to provide additional blood for follow-up cardiac biomarker tests at 6-12 hours and 18-24 hours after the initial index procedure. All of the following follow-ups are clinical follow-ups and do not involve invasive procedures. The benefit to the patient is a close and detailed follow-up after the procedure as compared to when the patient would not participate in the study.

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

For a subject to be enrolled in the study and considered for the index procedure, the following initial inclusion criteria must be met:
* Age > or <= 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.
* A maximum of one target lesion and one non-target lesion may be treated per subject. The lesions must be located in separate coronary arteries, with treatment of the non-target lesion occurring first using commercially available therapy (with exception of brachytherapy).
* 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
* Stroke or transient ischemic attack within the last 6 months prior to enrollment
* Intolerance to contrast agents that cannot be medically managed and/or intolerance to antiplatelet, anticoagulant or thrombolytic medications
* Refusal of blood transfusions
* 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:
* Documented diagnosis of an acute MI within 72 hours of the index procedure and an elevation of Troponin or CKMB above the URL (CKMB measurement is not required if CK is normal) at the time of the index procedure (99th percentile of the individual investigative site*s normal reference population)
* For subjects with stable angina and elevated Troponin, CKMB <99% URL is required
* ECG changes consistent with an acute MI within 72 hours of the index procedure. ECG changes consistent with an acute MI include:
* > 1 mm ST segment elevation or depression in consecutive leads
* New LBBB
* Development of pathological Q-waves in two contiguous leads of the ECG
* Acute coronary syndrome with baseline Troponin > 99% URL
* INR * 1.6
* Concomitant renal failure with serum creatinine level > 2.5 mg/dL
* Unresolved neutropenia (white blood cell count < 3,000 / µL), thrombocytopenia (platelet count < 100,000 / µL) or thrombocytosis (platelet count > 700,000 / µL)
* Unprotected left main CAD (> 50% diameter stenosis by operator visual estimate)
* Target vessel has been treated with any PCI procedure (e.g. PTCA, stent, cutting balloon, atherectomy, etc.) within 12 months prior to the index procedure
* 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
* 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 type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	PRO-Kinetic Energy - bare metal stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-03-2013
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	20-10-2016
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	NCT01612767
CCMO	NL42680.060.12

Study results

Date completed:	19-12-2017
Actual enrolment:	17