A Prospective, Randomized, Multicenter Trial to Assess an Everolimus-Eluting Coronary Stent System (PROMUS Element*) for the Treatment of up to two De Novo Coronary Artery Lesions

Published: 16-03-2009
Last updated: 06-05-2024

To determine the safety and effectiveness of the PROMUS Element* Everolimus-Eluting Coronary Stent System (Boston Scientific Corporation [BSC], Natick, MA) for the treatment of patients with up to 2 de novo atherosclerotic lesions

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

Summary

ID

NL-OMON33929

Source
ToetsingOnline

Brief title
PLATINUM

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures

Synonym
atherosclerosis, coronary disease

Research involving
Human

Sponsors and support

Primary sponsor: Boston Scientific Cooperation International
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: atherosclerotic lesions, drug-eluting stents, everolimus, native coronary arteries

Outcome measures

Primary outcome

Twelve-month target lesion failure (TLF) rate, defined as any ischemia-driven revascularization of the target lesion (TLR), myocardial infarction (MI, Q-wave and non-Q-wave) related to the target vessel, or cardiac death related to the target vessel.

Secondary outcome

Clinical endpoints measured in hospital and at 30 days, 6 months, 12 months, 18 months, 2 years, 3 years, 4 years, and 5 years in the RCT and non-randomized SV and LL subtrials:

• TLR rate

• TLF rate (primary endpoint at 12 months)

• Target vessel revascularization (TVR) rate

• Target vessel failure (TVF) rate

• MI (Q-wave and non-Q-wave) rate

• Cardiac death rate

• Non-cardiac death rate

• All death rate

• Cardiac death or MI rate

• All death or MI rate

• All death/MI/TVR rate

• Stent thrombosis rate (definite or probable by Academic Research Consortium

[ARC] definitions)

Periprocedural endpoints measured in the RCT and non-randomized SV and LL

subtrials:

• Technical success rate

Clinical procedural success rate

Study description

Background summary

The wide-spread use of drug-eluting stents has evolved as standard of care in de novo lesions. The proposed study will evaluate the safety and effectiveness of PROMUS Element for the treatment of de novo atherosclerotic lesions in native coronary arteries. The study design is consistent with the draft guidance for industry titled, *Coronary Drug-Eluting Stents - Nonclinical and Clinical Studies* (March 2008).

Study objective

To determine the safety and effectiveness of the PROMUS Element* Everolimus-Eluting Coronary Stent System (Boston Scientific Corporation [BSC], Natick, MA) for the treatment of patients with up to 2 de novo atherosclerotic lesions

Study design

The PROMUS Element clinical trial (PLATINUM) consists of the following.
• A randomized controlled trial (RCT) at up to 160 sites in the United States (US), Europe, Intercontinental (IC) region, and Japan aims to enroll 1,532 patients (1:1 randomization PROMUS Element to PROMUS) with a maximum of 2 workhorse (WH) de novo native coronary artery lesions <=24 mm in length (by visual estimate) in native coronary arteries >=2.50 mm to <=4.25 mm in diameter (by visual estimate). One de novo native coronary artery lesion within a different epicardial vessel that does not meet the WH selection criteria (see

Angiographic Inclusion Criteria) may also be treated during the index procedure, before the patient is enrolled, and before the target WH lesion is treated, provided that the patient has only one WH lesion.
• A concurrent, non-randomized, small vessel (SV) subtrial at up to 20 sites in the US and Japan aims to enroll 94 patients with a de novo native coronary artery lesion <=28 mm in length (by visual estimate) in a native coronary artery >=2.25 mm to <2.50 mm (by visual estimate). One SV lesion can be treated as part of the study. One de novo native coronary artery lesion within a different epicardial vessel (non-target lesion) may also be treated with a commercial treatment (eg, stent, balloon angioplasty, excluding brachytherapy) during the index procedure, before the patient is enrolled, and before the target SV lesion is treated.
• A concurrent, non-randomized, long lesion (LL) subtrial at up to 20 sites in the US and Japan aims to enroll 102 patients with a de novo native coronary artery lesion >24 mm and <=34 mm in length (by visual estimate) in a native coronary artery >=2.50 mm to <=4.25 mm (by visual estimate). One LL can be treated as part of the study. One de novo native coronary artery lesion within a different epicardial vessel (non-target lesion) may also be treated with a commercial treatment (eg, stent, balloon angioplasty, excluding brachytherapy) during the index procedure, before the patient is enrolled, and before the target LL is treated.

Intervention

PROMUS Element Everolimus-Eluting Coronary Stent System (PROMUS Element) or PROMUS* Everolimus-Eluting Coronary Stent System (PROMUS)

Study burden and risks

Burden:
Angiography, cardiac catherization and placement stent.
Benefits:
Dilatation and flow continuation of the cardiac vessels.
Risks equal general risks for stent implantation:
• Abrupt stent closure
• Acute myocardial infarction
• Allergic reaction to anticoagulants or antithrombotic therapy or contrast medium or stent materials including stent scaffold, polymer coating, or drug
• Aneurysm (coronary)
• Angina
• Arrhythmias, including ventricular fibrillation and ventricular tachycardia
• Arteriovenous fistula
• Cardiac tamponade
• Cardiogenic shock
• Death
• Dissection

• Emboli, distal (air, tissue, thrombotic, device materials, or stent delivery system materials)
• Heart failure
• Hematoma
• Hemorrhage, requiring transfusion
• Hypotension/hypertension
• Infection, local, and/or systemic
• Ischemia, myocardial
• Pain at the access site
• Perforation or rupture of one or more coronary arteries
• Pericardial effusion
• Pseudoaneurysm, femoral
• Pulmonary edema
• Renal failure
• Respiratory failure
• Restenosis of stented segment
• Shock
• Stent embolization
• Stent migration
• Stent thrombosis/occlusion
• Stroke/cerebrovascular accident/transient ischemic attack
• Total occlusion of coronary artery
• Vessel spasm
• Vessel trauma (dissection, perforation, rupture, or injury, including coronary) requiring surgical repair or reintervention.

Contacts

Public
Boston Scientific Cooperation International

100 Boston Scientific Way
Marlborough, MA 01752
US
Scientific
Boston Scientific Cooperation International

100 Boston Scientific Way
Marlborough, MA 01752
US

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Patient must be at least 18 years of age.
2. Patient has documented stable angina pectoris (Canadian Cardiovascular Society [CCS] Classification 1, 2, 3, or 4) or documented silent ischemia; or unstable angina pectoris (Braunwald Class IB-C, IIB-C, or IIIB-C
3. Patient has a left ventricular ejection fraction (LVEF) >=30% as measured within 30 days prior to enrollment
4. No more than 2 de novo target lesions in 2 separate native epicardial vessels may be treated, as described below under Multiple Interventions During Index Procedure. Multiple focal lesions may be treated if the lesions can be completely covered with 1 stent.
5. No more than 1 de novo non-target lesion in 1 non-target vessel may be treated, as described below under Multiple Interventions During Index Procedure. Multiple focal lesions may be treated if the lesions can be completely covered with 1 stent.
6. Target lesion must be located in a native coronary artery with a visually estimated reference vessel diameter (RVD) as follows:
o >=2.50 mm and <=4.25 mm for the RCT (WH selection criteria)
o >=2.25 mm and <2.50 mm for the non-randomized SV subtrial (SV selection criteria)
o >=2.50 mm and <=4.25 mm for the non-randomized LL subtrial (LL selection criteria)
7. Target lesion length must measure (by visual estimate):
o <=24 mm for the RCT (WH selection criteria)
o <=28 mm for the non-randomized SV subtrial (SV selection criteria)
o >24 mm and <=34 mm for the non-randomized LL subtrial (LL selection criteria)
8. Target lesion must be in a major coronary artery or branch with visually estimated stenosis >=50% and <100% with Thrombolysis in Myocardial Infarction (TIMI) flow >1.

Exclusion criteria

1. Patient has clinical symptoms and/or electrocardiogram (ECG) changes consistent with

acute MI.
2. Patient has had a known diagnosis of recent MI (ie, within 30 days prior to the index procedure) and has elevated enzymes at the time of the index procedure as follows.
o Patients are excluded if any of the following criteria are met at the time of the index procedure.
o If CK MB >2× upper limit of normal (ULN), the patient is excluded regardless of the CK Total.
o If CK MB is 1 2× ULN, the patient is excluded if the CK Total is >2× ULN.
o If CK Total/CK MB are not used and Troponin is, patients are excluded if the following criterion is met at the time of the index procedure.
o Troponin >1× ULN with at least one of the following.
o Patient has ischemic symptoms and ECG changes indicative of ongoing ischemia (eg, >1 mm ST segment elevation or depression in consecutive leads or new left bundle branch block [LBBB]);
o Development of pathological Q waves in the ECG; or
o Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality.
3. Patient has received an organ transplant or is on a waiting list for an organ transplant.
4. Patient is receiving or scheduled to receive chemotherapy within 30 days before or after the index procedure.
5. Patient is receiving immunosuppressive therapy or has known immunosuppressive or autoimmune disease (eg, human immunodeficiency virus, systemic lupus erythematosus, etc.).
6. Patient is receiving chronic (>=72 hours) anticoagulation therapy (eg, heparin, coumadin) for indications other than acute coronary syndrome.
7. Patient has a platelet count <100,000 cells/mm3 or >700,000 cells/mm3.
8. Patient has a white blood cell (WBC) count <3,000 cells/mm3.
9. Patient has documented or suspected liver disease, including laboratory evidence of hepatitis.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-05-2009
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	drug-eluting stent
Registration:	No

Ethics review

Approved WMO Date:	16-03-2009
Application type:	First submission
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	NL25802.060.08