# A Prospective, Randomized, Multi-center Trial to Assess the Everolimus-Eluting Coronary Stent System (PROMUS Element) for Coronary Revascularization in a Population of Unrestricted Patients

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To determine the safety and effectiveness of Boston Scientific*s Everolimus-eluting coronary stent system (PROMUS Element*) for coronary revascularization in an unrestricted population compared to the Xience* Prime control.

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

## Summary

### ID

NL-OMON35665

**Source**
ToetsingOnline

**Brief title**
PLATINUM-PLUS

### Condition

- Coronary artery disorders

**Synonym**
Coronary artery disease; atherosclerotic heart disease

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** European Cardiovascular Research Center CERC
**Source(s) of monetary or material Support:** Beurs van Boston Scientific (investigator-initiated),Boston Scientific Cooperation International

## Intervention

**Keyword:** Coronary Artery Disease, Drug-eluting stents, Randomized

## Outcome measures

### Primary outcome

Target Vessel failure (TVF) of the PROMUS Element* Everolimus-Eluting Coronary

Stent at 12 months post-procedure. TVF is defined as any ischemia-driven

revascularization of the target Vessel (TVR), MI (Q-wave and non-Q-wave)

related to the target vessel, or cardiac death related to the target vessel.

### Secondary outcome

Secondary Endpoints:

Clinical endpoints will be measured at 30 days, 12 months and 2 years, and :

* Ischemia Driven Target Lesion Revascularization (TLR) rate

* Ischemia Driven Target Vessel Revascularization (TVR) rate

* Target Lesion Failure (TLF) rate: defined as any ischemia-driven

revascularization of the target lesion (TLR), MI (Q-wave and non-Q-wave)

related to the target vessel, or cardiac death related to the target vessel

* Myocardial Infarction (MI) rate: Q-wave and non-Q-wave, cumulative and

individual

* Cardiac death rate

* Non-cardiac death rate

* All death or MI rate

* All Death/MI/TVR rate

* Major Adverse Cardiac Event (MACE) rate defined as a composite of death, MI (Q wave or non-Q wave), emergent coronary artery bypass surgery (CABG), or target lesion revascularization (TLR) by repeat PTCA or CABG.

* Stent Thrombosis (ST) rate using ARC definition of definite and probable stent thrombosis and categorized as early, late or very late.

Procedural Endpoints:

* Device success, defined as attainment of <30% residual stenosis of the target lesion (visual assessment) using the PROMUS Element* or Xience* Prime stent.

* Lesion success defined as attainment of < 30% residual stenosis (visual assessment) using any percutaneous method.

* Procedure success defined as lesion success without the occurrence of in-hospital MACE.

* Procedure complication rate including composite and individual angiographic occurrence of dissection >B, distal embolization, no reflow, slow flow, abrupt closure, or perforation.

# Study description

**Background summary**

The PLATINUM-PLUS trial will investigate in a broad patient and lesion population, the CE Mark approved PROMUS Element* Everolimus-Eluting Coronary Stent System (PROMUS Element), which combines the Element* stent (the latest generation stent from Boston Scientific Corporation [BSC, Natick, Massachusetts, United States]), everolimus, and the poly (n-butyl methacrylate) (PBMA) and poly (vinylidene fluoride-co-hexafluoropropylene) (PVDF-HFP)

polymers. The PROMUS Element, received CE Mark on November 3rd 2009; it is currently under investigation in the PLATINUM clinical trial, and has great promise as it combines BSC*s novel stent technology with the everolimus drug and polymers that have demonstrated excellent performance in the SPIRIT clinical program.

### Study objective

To determine the safety and effectiveness of Boston Scientific*s Everolimus-eluting coronary stent system (PROMUS Element*) for coronary revascularization in an unrestricted population compared to the Xience* Prime control.

### Study design

The PROMUS Element* clinical trial (PLATINUM-PLUS) consists of a randomized controlled trial (RCT) in the European Union (EU) and Switzerland which will enroll approximately 2980 subjects (2:1 randomization PROMUS Element*: Xience* Prime) in a Population of consecutive, all comers in the reimbursed indications per-country. All subjects will be screened per the protocol required inclusion/exclusion criteria.

### Intervention

2:1 randomization for treatment with PROMUS Element* Everolimus-Eluting Coronary Stent or treatment with Xience* Prime Everolimus-Eluting Coronary Stent

### Study burden and risks

No extra risks are associated with partaking in this study when compared to standard treatment.

There is a marginal additional burden due to the follow-up, however every effort is made to combine this follow-up with regular controls.

No additional benefits are expected from partaking in this study except of course a possible improvement in the treatment of future new disease.

## 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. The patient must be >=18 of age
2. Symptomatic ischemic heart disease (CCS class 1-4, Braunwald Class IB, IC, and/or objective evidence of myocardial ischemia);
3. Acceptable candidate for CABG;
4. The patient is willing to comply with specified follow-up evaluations;
5. The patient or legally authorized representative has been informed of the nature of the study, agrees to its provisions and has been provided written informed consent, approved by the appropriate Medical Ethics Committee (MEC).
6. Single or multiple native coronary artery or saphenous vein graft lesions in single or multiple vessels;
7. Patients with multi-lesion or multi-vessel coronary disease may undergo staged (planned) procedures within 42-days of the index procedure.
8. Reference vessel diameter must be >=2.25 to <= 4.25 mm by visual estimate.

## Exclusion criteria

1. Pregnant or nursing subjects and those who plan pregnancy in the period up to 1 year

following index procedure. Female subjects of child-bearing potential must have a negative pregnancy test done within 7 days prior to the index procedure per site standard test;
2. Patients in whom anti-platelet and/or anticoagulant therapy is contraindicated;
3. Patient has other medical illness (e.g., cancer, known malignancy , congestive heart failure, organ transplant recipient or candidate) or known history of substance abuse (alcohol, cocaine, heroin etc.) that may cause non-compliance with the protocol, confound the data interpretation or is associated with a limited life expectancy (i.e., less than 1 year);
4. Patient has a known hypersensitivity or contraindication to aspirin, heparin/bivalirudin, clopidogrel/ticlopidine, prasugrel, platinum chromium alloy, everolimus, and/or contrast sensitivity that cannot be adequately pre-medicated;
5. Patient with LVEF <20%, cardiogenic shock, or hemodynamic compromise requiring pressors or inotropes or mechanical support devices
6. Any significant medical condition which in the Investigator*s opinion may interfere with the patient*s optimal participation in the study;
7. Currently participating in another investigational drug or device study.

# Study design

## Design

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|---|---|
| Study phase: | 4 |
| 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): | 06-01-2012 |
| Enrollment: | 100 |
| Type: | Actual |

## Medical products/devices used

| | |
|---|---|
| Generic name: | Stent |

| | |
|---|---|
| Registration: | Yes - CE intended use |

## Ethics review

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|---|---|
| Approved WMO Date: | 22-12-2011 |
| Application type: | First submission |
| Review commission: | TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam) |

## 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 | NCT01342822 |
| CCMO | NL38465.101.11 |