PE-Prove Study
PROMUS* Element* Everolimus-Eluting Coronary Stent System
European Post-Approval Surveillance Study
A prospective, open label, multi-center observational study

Published: 03-02-2011
Last updated: 03-05-2024

Please see pages 3-5 of the Protocol

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

Summary

ID

NL-OMON34092

Source
ToetsingOnline

Brief title
PE-Prove study

Condition

- Coronary artery disorders

Synonym
Coronary artery disease ; Narrowing of arteries

Research involving

Human

Sponsors and support

Primary sponsor: Boston Scientific International S.A.
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Coronary artery disease, Drug-eluting stent, Percutaneous Transluminal Coronary Angioplasty

Outcome measures

Primary outcome

Please see pages 3-5 of the Protocol

Secondary outcome

Please see pages 3-5 of the Protocol

Study description

Background summary

Please see pages 3-5 and 9 of the Protocol

Study objective

Please see pages 3-5 of the Protocol

Study design

Please see pages 3-5 of the Protocol

Study burden and risks

As all procedures are part of the routine care the only risk in participating in this study is the additional blood test.
The risks associated with providing a blood sample can include fainting, pain (a painful jab as the needle is inserted into the arm) and/or bruising. In rare cases, it is also possible for a blood clot to form or for an infection to

occur at the site where the needle was inserted.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients who are candidates for Coronary artery stenting, signed the Informed Consent Form and are eligible to receive a PROMUS* Element* stent will be evaluated for enrollment in this study.

Exclusion criteria

No study-specific exclusion criteria apart from any contra-indications

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-03-2011
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	03-02-2011
Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	28-02-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)
Approved WMO Date:	05-05-2011
Application type:	Amendment
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen

(Wijchen)

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	NCT01148329
CCMO	NL33913.072.10