A Prospective Multicenter Trial to Assess the Safety and Effectiveness of the SYNERGYTM Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGYTM Stent System) for the Treatment of Atherosclerotic Lesion(s)

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To assess the safety and effectiveness of the SYNERGYTM Coronary Stent System for the treatment of subjects with atherosclerotic lesion(s) * 34 mm in length (by visual estimate) in native coronary arteries *2.25 mm to *4.0 mm in diameter (by visual...

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

Summary

ID

NL-OMON39360

Source
ToetsingOnline

Brief title
EVOLVE II - Device study - Boston Scientific

Condition

- Coronary artery disorders

Synonym
Symptomatic coronary artery disease or documented silent ischemia

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Atherosclerosis, Drug-eluting stent, Everolimus

Outcome measures

Primary outcome

* The primary endpoint for the RCT and the Diabetes subtrial is the 12-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.

* There is no primary endpoint for the PK subtrial as it is an observational trial.

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 the PK and Diabetes subtrials:

* TLR rate

* TLF rate (primary endpoint at 12 months for the RCT and the Diabetes subtrial)

* 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)

* Longitudinal stent deformation rate assessed by an independent angiographic core laboratory

Periprocedural endpoints:

* Technical success rate

* Clinical procedural success rate

* Longitudinal stent deformation assessed by an independent angiographic core laboratory

PK parameters calculated for subjects in the PK subtrial:

* Maximum observed blood concentration (Cmax)

* First time of occurrence of Cmax (tmax)

* Terminal phase rate constant (*z)

* Terminal phase half-life (t*) calculated as t* = ln(2/*z)

* Area under the blood concentration versus time curve from time zero to 1 hour (AUC0 1), time zero to 24 hours (AUC0 24), time zero to last quantifiable concentration (AUC0 t), and extrapolated to infinity (AUC0 *)

* Percentage of AUC0 * obtained by extrapolation (%AUCex)

* Total blood clearance (CL)

Study description

Background summary

The SYNERGY Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY Stent System), manufactured by BSC, is a device/drug combination product comprised of two regulated components: a device (Coronary Stent System) and a drug product (a formulation of everolimus contained in a bioabsorbable polymer coating). This trial is performed to assess the safety and effectiveness compared with the control device PROMUS Element Plus.

Study objective

To assess the safety and effectiveness of the SYNERGYTM Coronary Stent System for the treatment of subjects with atherosclerotic lesion(s) * 34 mm in length (by visual estimate) in native coronary arteries *2.25 mm to *4.0 mm in diameter (by visual estimate)

Study design

The EVOLVE II clinical trial consists of the following:
* A prospective, multicenter, 1:1 randomized (SYNERGY to PROMUS Element Plus), controlled, single-blind, non-inferiority trial (RCT)
* A concurrent, non-randomized, single-arm, pharmacokinetic (PK) subtrial
* A consecutive, non-randomized, single-arm, Diabetes subtrial
Note: A subject can be enrolled in the RCT, the PK subtrial, or the Diabetes subtrial. A subject cannot be enrolled in more than one of these trials.

Intervention

* In the RCT, after subjects meet trial selection criteria they will be randomized to receive either the test device or a control device in an equal (1:1) allocation. Randomization will be stratified by diabetic status (presence or absence of medically treated diabetes), as well as by site.
* In the PK and Diabetes subtrials, subjects will be enrolled in a non-random fashion.

Study burden and risks

The SYNERGY stent is expected to be suitable for its intended purpose. There are no unacceptable residual risks/intolerable risks and all applicable risks have been addressed through the provision of appropriate Directions for Use. Evaluation of the risks and benefits that are expected to be associated with use of the SYNERGY stent demonstrate that when used under the conditions intended, the benefits associated with use of the SYNERGY stent should outweigh the risks.

Safety and performance of the Element stent platform and everolimus has been demonstrated in the PLATINUM Clinical Trial program.

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

Clinical Inclusion criteria
CI1. Subject must be at least 18 years of age
CI2. Subject (or legal guardian) understands the trial requirements and the treatment procedures and provides written informed consent before any trial-specific tests or procedures are performed
CI3. For subjects less than 20 years of age enrolled at a Japanese site, the subject and the subject*s legal representative must provide written informed consent before any study-specific tests or procedures are performed
CI4. Subject is eligible for percutaneous coronary intervention (PCI)
CI5. Subject has symptomatic coronary artery disease or documented silent ischemia
CI6. Subject is an acceptable candidate for coronary artery bypass grafting (CABG)
CI7. Subject is willing to comply with all protocol-required follow-up evaluation;Angiographic Inclusion Criteria (visual estimate)
AI1. Target lesion(s) must be located in a native coronary artery with a visually estimated reference vessel diameter (RVD) *2.25 mm and *4.0 mm
AI2. Target lesion(s) length must be *34 mm (by visual estimate)
AI3. Target lesion(s) must have visually estimated stenosis *50% and <100% with thrombolysis in Myocardial Infarction (TIMI) flow >1
AI4. Coronary anatomy is likely to allow delivery of a study device to the target lesions(s)
AI5. The first lesion treated must be successfully pre-dilated
Note: Successful predilatation refers to dilatation with a balloon catheter of appropriate length, diameter, and placement to cover the lesion and inflated with enough pressure to dilate said lesion with no greater than 50% residual stenosis and no dissection greater than National Heart, Lung, Blood Institute (NHLBI) type C.

Exclusion criteria

Clinical Exclusion Criteria
CE1. Subject has clinical symptoms and/or electrocardiogram (ECG) changes consistent with acute ST elevation MI (STEMI)
CE2. Subject has cardiogenic shock, hemodynamic instability requiring inotropic or mechanical circulatory support, intractable ventricular arrhythmias, or ongoing intractable angina
CE3. Subject has received an organ transplant or is on a waiting list for an organ transplant
CE4. Subject is receiving or scheduled to receive chemotherapy within 30 days before or after the index procedure
CE5. Planned PCI or CABG after the index procedure
CE6. Subject has a known allergy to the trial stent system or protocol-required concomitant medications (e.g., platinum, platinum-chromium alloy, stainless steel, everolimus or structurally related compounds, polymer or individual components, all P2Y12 inhibitors, or aspirin) and contrast (that cannot be adequately premedicated)
CE7. Subject has a known condition(s) of the following (as assessed from the time of

screening through the day of index procedure):
o Other serious medical illness (e.g., cancer, congestive heart failure) that may reduce life expectancy to less than 24 months
o Current problems with substance abuse (e.g., alcohol, cocaine, heroin, etc.)
o Planned procedure that may cause non-compliance with the protocol or confound data interpretation
CE8. Subject is participating in another investigational drug or device clinical trial that has not reached its primary endpoint
CE9. Subject intends to participate in another investigational drug or device clinical trial within 12 months after the index procedure
CE10. Subject with known intention to procreate within 12 months after the index procedure (women of child-bearing potential who are sexually active must agree to use a reliable method of contraception from the time of screening through 12 months after the index procedure)
CE11. Subject is a woman who is pregnant or nursing (a pregnancy test must be performed within 7 days prior to the index procedure in women of child-bearing potential);Angiographic Exclusion Criteria (visual estimate)
AE1. Planned treatment of more than 3 lesions
AE2. Planned treatment of lesions in more than 2 major epicardial vessels
AE3. Planned treatment of a single lesion with more than 1 stent
AE4. Subject has 2 target lesions in the same vessel that are separated by less than 15 mm (by visual estimate)
AE5. Target lesion(s) is located in the left main
AE6. Target lesion(s) is located within a saphenous vein graft or an arterial graft
AE7. Target lesion(s) will be accessed via a saphenous vein graft or arterial graft
AE8. Target lesion(s) with a TIMI flow 0 (total occlusion) or TIMI flow 1 prior to guide wire crossing
AE9. Target lesion(s) treated during the index procedure that involves a complex bifurcation (e.g., bifurcation lesion requiring treatment with more than 1 stent)
AE10. Target lesion(s) is restenotic from a previous stent implantation
AE11. Subject has unprotected left main coronary artery disease (>50% diameter stenosis)

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):	07-05-2013
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	SYNERGY Stent System
Registration:	No

Ethics review

Approved WMO Date:	18-03-2013
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	27-06-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	31-07-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	28-07-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-06-2017
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	19-09-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-08-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NCT01665053
CCMO	NL40711.044.12