A Clinical Evaluation of the XIENCE TM V Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Coronary Artery Lesions

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The purpose of this Clinical Evaluation is a continuation in the assessment of the performance of the XIENCE* V Everolimus Eluting Coronary Stent System (XIENCE* V EECSS) in the treatment of patients with de novo coronary artery lesions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Interventional

Summary

ID

NL-OMON29915

Source
ToetsingOnline

Brief title
SPIRIT V

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
coronary artery lesions

Research involving
Human

Sponsors and support

Primary sponsor: Abbott

Source(s) of monetary or material Support: Abbott Vascular Europe S.A.

Intervention

Keyword: clinical evaluation, drug-eluting stent, Everolimus

Outcome measures

Primary outcome

The primary endpoint of the SPIRIT V Diabetic Study is in-stent Late Loss (LL) at 270 days.

The primary endpoint of the SPIRIT V Registry is Adjudicated Composite rate of All Death, Myocardial Infarction (MI) and Target Vessel Revascularization (TVR) at 30 days.

Secondary outcome

SPIRIT V Diabetic Study:

Acute Success (Clinical Device Success and Clinical Procedure Success);

Adjudicated Stent Thrombosis at 30 days, 240 days, 1, 2, 3, 4 and 5 years:(Confirmed/definite, Probable, Possible)

In-segment, proximal and distal Late Loss at 270 days: In-stent and in-segment Angiographic Binary Restenosis rates at 270 days; In-stent and in-segment percent Diameter Stenosis at 270 days; Adjudicated Target Lesion Revascularization (TLR) rate at 30 days, 240 days, 1, 2, 3, 4 and 5 years (both Clinical-indicated and not clinical-indicated); Adjudicated Composite rate of Cardiac Death, Myocardial Infarction (MI) and Clinical-indicated Target Lesion; Revascularization (CI-TLR) at 30 days, 240 days, 1, 2, 3, 4 and 5 years; Adjudicated Composite rate of All Death, Myocardial Infarction (MI) and Target Vessel Revascularization (TVR) at 30 days, 240 days, 1, 2, 3, 4 and 5 years.

The primary endpoint of the SPIRIT V Registry is Adjudicated Composite rate of

All Death, Myocardial Infarction (MI) and Target Vessel Revascularization (TVR)

at 30 days.

Spirit V Registry:

Acute Success (Clinical Device Success and Clinical Procedure Success);

Adjudicated Stent Thrombosis at 30 days, and at 1 and 2 years

(Confirmed/definite, Probable, Possible)

Adjudicated TLR at 30 days, 1 and 2 years; Adjudicated Composite rate of

Cardiac Death, MI and CI-TLR at 30 days, 1 and 2 years; Adjudicated Composite

rate of All Death, MI and TVR at 1 and 2 years

Study description

Background summary

Stenting of de novo lesions in native coronary arteries has been shown to be a safe and effective treatment of occlusion due to atherosclerosisis. However, many interventional cardiologists believe that restenosis following stenting is the most significant and pressing problem in the field of interventional cardiology today.
Various therapies intended to reduce the rate of restenosis have been tested in clinical studies and in clinical practice. These methods include the use of various sources of radiation as well as the local delivery or application of an anti-proliferative drug to the lesion site. The current research focus is aimed at assessing the efficacy and safety of implanting coronary stents coated with various doses or formulations of drugs to reduce neointimal proliferation.

The fact that everolimus has shown safety and efficacy in feasibility studies with widely varying stent platforms, coating systems and release profiles, provides evidence of safety for further evaluation in larger studies.
Spirit V consists of two parts, the Spirit V Diabetic study and the Spirit V Registry.

The data gathered in the Spirit V Diabetic study will allow further and more

specific investigation of the diabetic population - both insulin dependent and non-insulin dependent - with a higher incidence of more complex lesions and a higher risk of developing cardiac events. This clinical evaluation will therefore provide a significant complement to the performance data obtained from the randomized clinical trials.

In the Spirit V Registry more complex and challenging lesions will be studied, compared to Spirit First and Spirit II, in a real-life treatment setting according to criteria as described in the Instructions for Use (IFU) (Appendix B).

Study objective

The purpose of this Clinical Evaluation is a continuation in the assessment of the performance of the XIENCE* V Everolimus Eluting Coronary Stent System (XIENCE* V EECSS) in the treatment of patients with de novo coronary artery lesions.

Study design

The SPIRIT V Clinical Evaluation consists of two concurrent studies, the Diabetic Study and the Registry. The SPIRIT V Diabetic Study is a prospective, randomized, active-controlled, single blind, parallel two-arm multi-center study comparing the XIENCE* V EECSS to the TAXUS® Liberté* in the treatment of diabetic patients with coronary artery lesions who will fulfill the eligibility criteria. The SPIRIT V Registry is a prospective, single arm, multi-center registry evaluating performance of the XIENCE* V EECSS in real-world use, per its Instruction For Use (IFU).

The study will be conducted in up to 150 study centers outside of the United States. Approximately 3,000 patients will be enrolled in the study:

300 patients will be randomized (2:1) in the Spirit V Diabetic study against the TAXUS® Liberté* Coronary Stent System. These patients will be recruited in 30 selected sites only.
2700 patients will be enrolled in the Spirit V Registry.

Intervention

The treatment strategy for all patients enrolled in the Spirit V Diabetic study is as follows:
Patients may receive up to 4 planned stents, depending on the number of vessels treated and their respective lesion lengths. Maximum of one de novo, native target lesion per major epicardial vessel or side branch (no prior stent implant, no prior brachytherapy)

The treatment strategy for all patients enrolled in the Spirit V Registry is as follows:
Patients may receive up to 4 planned XIENCE V* EECSS stents depending on the number of vessels treated and their respective lesion lengths

Study burden and risks

Potential Risks: Risks from Cardiac Catheterization, Stenting and Percutaneous Transcatheter Coronary Angioplasty
Associated Risks of Everolimus: Everolimus is extensively metabolized by the cytochrome P4503A4 (CYP3A4) in the gut wall and liver and is a substrate for the countertransporter P-glycoprotein. Therefore, absorption and subsequent elimination of everolimus may be influenced by drugs that affect these pathways. Everolimus has also been shown to reduce the clearance of some prescription medications when it was administered orally along with cyclosporine (CsA). Formal drug interaction studies have not been performed with XIENCE* V Everolimus Eluting Coronary Stent System. Therefore, due consideration should be given to the potential for both systemic and local drug interactions in the vessel wall when deciding to place the XIENCE* V Everolimus Eluting Coronary Stent in a subject taking a drug with known interaction with everolimus.

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

Maximum of one, de novo, target lesion per native major epicardial vessel or side branch (no prior stent implant, no prior brachytherapy
Target vessel reference diameter must be between 2.5 mm and 4.0 mm by visual estimate
Target lesion <28 mm in length by visual estimation
Target lesion must be in a major artery or branch with a visually estimated stenosis of >50% and <100% and a TIMI flow>1
Spirit V Registry: According tot he instructions for Use (IFU)

Exclusion criteria

Patient has had a known diagnosis of acute myocardial infarction within 72 hours preceding the index procedure
Patient has current unstable arrhythmias
Patient has a known left ventricular ejection fraction <30%
Spirit V Registry: According to the instructions for Use (IFU)

Study design

Design

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):	31-10-2006
Enrollment:	225
Type:	Actual

Ethics review

Approved WMO Date:	10-10-2006
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	NL13612.060.06