A Continuation in the Clinical Evaluation of the Abbott Vascular Everolimus-Eluting Bioresorbable Vascular Scaffold in the Treatment of Subjects with de novo Native Coronary Artery Lesions

Published: 25-03-2010
Last updated: 04-05-2024

The primary objective of the ABSORB EXTEND trial is to continue the assessment of the safety and performance of the BVS EECSS Gen 1.1 in a population of up to 1,000 subjects with a maximum of two de novo native coronary artery lesions each located...

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

Summary

ID

NL-OMON38187

Source
ToetsingOnline

Brief title
ABSORB EXTEND

Condition

- Coronary artery disorders

Synonym
coronary heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Abbott Vascular International
Source(s) of monetary or material Support: Ministerie van OC&W,Medisch hulpmiddelen bedrijf

Intervention

Keyword: Bioresorbable scaffold, Coronair sclerose, PCI

Outcome measures

Primary outcome

Acute success (clinical device and clinical procedure);

Cardiac Death at 30, 180 days, and 1, 2, and 3 years;

Myocardial Infarction at 30, 180 days, and 1, 2, and 3 years;

Target Vessel Myocardial Infarction at 30, 180 days, and 1, 2, and 3 years;

Ischemia Driven MACE at 30, 180 days, and 1, 2, and 3 years;

Ischemia driven Target Vessel Failure at 30, 180 days, and 1, 2, and 3 years;

Ischemia Driven Target Lesion Revascularization at 30, 180 days and 1, 2, and 3

years;

Ischemia Driven Target Vessel Revascularization at 30, 180 days and 1, 2, and 3

years;

Stent thrombosis at 30, 180 days, and 1, 2, and 3 years.

Secondary outcome

Descriptive analysis of strut, lesion and vessel morphology post-procedure and

at 2 years;

Lumen area post-procedure and at 2 years;

Minimum luminal area (MLA) post-procedure and at 2 years;

In-stent Late Loss (LL) at 2 years;

In-segment LL at 2 years;

Proximal LL (proximal defined as within 5 mm of tissue proximal to stent

placement) at 2 years;

Distal LL (distal defined as within 5 mm of tissue distal to stent placement)

at 2 years;

In-stent and in-segment Minimum Luminal Diameter (MLD) post-procedure and at 2

years;

In-stent and in-segment % Diameter Stenosis (DS) post-procedure and at 2 years;

In-stent and in-segment Angiographic Binary Restenosis (ABR) rate at 2 years;

Aneurysm, thrombus, persisting dissection at 2 years;

Vessel area post-procedure and at 2 years;

In-stent %Volume Obstruction (VO) at 2 years.

Study description

Background summary

The ABSORB EXTEND Clinical Investigation Plan 09-386 (version 2.0, 15 March, 2010) is a continuation in the assessment of safety and performance of the BVS Everolimus Eluting Coronary Stent System (BVS EECSS) in the treatment of subjects with a maximum of two de novo native coronary artery lesions located in two different major epicardial vessels. The ABSORB EXTEND trial is intended to expand the treatment to a larger subject population to receive the BVS EECSS, following the completion of enrollment of 110 subjects in the ongoing First in Man ABSORB Clinical Investigation (ABSORB), including subjects with longer lesions.
Subjects enrolled in ABSORB EXTEND will receive the BVS EECSS Gen 1.1 scaffold. This scaffold is currently under evaluation in the approximately 80 subjects who are planned to be enrolled in Cohort B of ABSORB, which was initiated on

March 19, 2009, and is currently enrolling. The BVS EECSS Gen 1.1 is similar to the BVS EECSS Gen 1.0 that was evaluated in the first 30 subjects who compose Cohort A of ABSORB.

Study objective

The primary objective of the ABSORB EXTEND trial is to continue the assessment of the safety and performance of the BVS EECSS Gen 1.1 in a population of up to 1,000 subjects with a maximum of two de novo native coronary artery lesions each located in different epicardial vessels. The ABSORB EXTEND trial is intended to expand the treatment to subjects with longer lesions than those in the ABSORB trial.

Study design

Prospective, single-arm, open-labeled clinical investigation

Intervention

Placement of the scaffold study will not differ from a routine stent procedure (other than the use of a non-CE marked stent). Post-placement of the scaffold includes IVUS and OCT (this is optional, but it is to be expected that the Erasmus MC will participate in this substudy). Apart from a telephone follow-up (or outpatients), a MSCT will be done after 18 months and 2 years after the initial procedure a repeat angio, including IVUS and OCT will be performed.

Study burden and risks

The potential risks do not differ from the risks associated with routine stent procedures as described in the brochure of the Dutch Heart Foundation.
Death-0.2-0.5%
Myocardial infarction during the intervention
Hematoma (groin/ arterial sheath)
Major bleeding caused by the administration of anticoagulants during and after treatment

In addition to this, is it important to note that patients undergo during the follow-up phase a repeat angio. The risk of this repeat angio is also mentioned in the brochure of the Heart Foundation.

Contacts

Public
Abbott Vascular International

Park Lane, Culliganlaan 2B
Diegem 1831
BE
Scientific
Abbott Vascular International

Park Lane, Culliganlaan 2B
Diegem 1831
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-) =< 2 de novo lesions can be treated, each located in a separate native epicardial vessel.
-) Target lesion(s) must measure <= 28 mm in length.
-) Target lesion(s) must be in a major artery or branch with a visually estimated stenosis of >= 50% and < 100% with a TIMI flow of >= 1.
-) Percutaneous interventions for lesions in a non-target vessel are allowed if done >= 30 days prior to or if planned to be done 6 months after the index procedure.

Exclusion criteria

-) Lesion(s) located within an arterial or saphenous vein graft or distal to a diseased (defined as vessel irregularity per angiogram and > 20% stenosed lesion by visual estimation) arterial or saphenous vein graft.
-) Lesion(s) involving a bifurcation with side branch vessel >= 2 mm in diameter, ostial lesion > 40% stenosed by visual estimation or side branch requiring predilatation.
-) Total occlusion (TIMI flow 0), prior to wire passing.
-) Target vessel(s) contains visible thrombus.
-) Another clinically significant lesion is located in the same epicardial vessel (including side

branch) as the target lesion(s).
-) Subject has received brachytherapy in any epicardial vessel (including side branches).

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-04-2010
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	Coronary stent
Registration:	No

Ethics review

Approved WMO Date:	25-03-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-06-2010
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	21-07-2011
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	08-02-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-10-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-09-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	24-06-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	05-10-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (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
CCMO	NL30435.078.09