A clinical evaluation to compare the safety, efficacy and performance of ABSORB everolimus eluting bioresorbable vascular scaffold against XIENCE PRIME everolimus eluting coronary stent system in the treatment of subjects with ischemic heart disease caused by de novo native coronary artery lesions

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To compare the safety, effectiveness and performance of TM ABSORB bioabsorbable everolimus eluting vascular scaffold against XIENCE PRIME TM everolimus eluting coronary stent system in treating people with ischemic heart disease caused by de novo...

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

Summary

ID

NL-OMON39935

Source
ToetsingOnline

Brief title
BVS absorb II

Condition

- Coronary artery disorders

Synonym
angina pectoris, ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Abbott Vascular International BVBA
Source(s) of monetary or material Support: medische hulpmiddelen bedrijf

Intervention

Keyword: coronary, pci, scaffold

Outcome measures

Primary outcome

• Vasomotion assessed by change in Mean Lumen Diameter between pre- and

post-nitrate at 3 years (superiority)

• Minimum Lumen Diameter (MLD) at 3 years post nitrate minus MLD post procedure

post nitrate (non-inferiority, reflex to superiority)

Secondary outcome

-) Acute success, including stent success (lesion analysis) and procedural

success (subject analysis)

-) Clinical endpoints (after 30 days, 180 days, 1-5 years follow up),

including: death (cardiac, vascular, not cardiovascular), myocardial infarction

(MI: QMI and NQMI) , revascularization

-) Composite endpoints, including: Death / MI all, Cardiac death

-) Scaffold-/stenttrombose, incl timing (acute, subacute, late and very late)

-) Quality of Life (QoL)

Study description

Background summary

The ABSORB II Randomized Controlled Trial (RCT) is designed to continue the safety and efficacy of the ABSORB scaffold to evaluate and to compare XIENCE PRIME. To date, no direct comparison between drugeluting absorbable metal stents and drugeluting performed. In addition, the evaluation of the scaffold ABSORB currently limited to relatively simple low complex lesions. The treatment in this randomized trial will be subjects with a longer length lesions, wherein overlapping stents and smaller target vessels in the target group.

Study objective

To compare the safety, effectiveness and performance of TM ABSORB bioabsorbable everolimus eluting vascular scaffold against XIENCE PRIME TM everolimus eluting coronary stent system in treating people with ischemic heart disease caused by de novo native coronary artery lesions.

In three participating sites in The Netherlands patients who are scheduled for a re-catheterisation after 3 years will be asked to participate in a sub-study called Physiological sub-study (Pressure/Velocity measurement), a total of 30 patiënts will be asked. The aim of this sub-study is to provide physiological information on the microvasculature function of the patients that participate in the Absorb II study.

Study design

The ABSORB II Randomized Controlled Trial (RCT) is a prospective, randomized (2:1; ABSORB versus XIENCE PRIME), active-controlled, single-blind, parallel two-arm, multicenter clinical trial. A total of about 501 people (334 in the ABSORB group and 167 in the XIENCE PRIME group) will be randomized in approximately 40 locations in Europe. The test can treat up to two de novo native coronary artery lesions, each in different major epicardial coronary arteries, with a Dmax by online QCA >= 2.25 mm to <= 3.3 mm and lesion length <= 48 mm.

Intervention

Patients randomised in the scaffold group are treated with a bioabsorbable scaffold, the control group patients with a Xience stent. During the procedure

also IVUS and lipiscan (Erasmus) imaging will be performed. Follow-up visits include exercise testings, blood tests, QoL, diary, MSCT (scaffold group), and angiography.

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

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

• Subject must be at least 18 years of age and less than 85 years of age.
• Subject must agree not to participate in any other clinical investigation for a period of three years following the index procedure. This includes clinical trials of medications and invasive procedures. Questionnairebased studies, or other studies that are non-invasive and do not require medication are allowed.
• Subject is able to verbally confirm understanding of risks, benefits and treatment alternatives of receiving the ABSORB scaffold and he/she or his/her legally authorized representative provides written informed consent prior to any Clinical Investigation related procedure, as approved by the appropriate Ethics Committee
• Subject must have evidence of myocardial ischemia (e.g., stable or unstable angina, silent ischemia).
• Subject must be an acceptable candidate for coronary artery bypass graft (CABG) surgery
• Subject must agree to undergo all clinical investigation plan-required follow-up visits, exercise testing, blood draw as well as adherence to ESC Guidelines and completion of quality of life questionnaires and of a subject diary to collect information including but not limited to tobacco usage, food intake, daily exercise and body weight.;Angiographic Inclusion Criteria
• One or two de novo native lesions each located in a different epicardial vessel.
• If two treatable lesions meet the eligibility criteria, they must be in separate major epicardial vessels (LAD with septal and diagonal branches, LCX with obtuse marginal and/or ramus intermedius branches and RCA and any of its branches).
• Target lesion(s) must have a visually estimated diameter stenosis of >=50% and <100% with a TIMI flow of >= 1.
• Lesion(s) must be located in a native coronary artery with Dmax by online QCA of >= 2.25 mm and <= 3.3 mm.
• Lesion(s) must be located in a native coronary artery with lesion(s) length by on-line QCA of <= 48 mm.
• Percutaneous interventions for lesions in a non-target vessel are allowed if done >=30 days prior to or if planned to be done 2 years after the index procedure.
• Percutaneous intervention for lesions in the target vessel are allowed if done >6 months prior to or if planned to be done 2 years after the index procedure.

Exclusion criteria

General Exclusion Criteria
• Known hypersensitivity or contraindication to aspirin, both heparin and bivalirudin, antiplatelet medications specified for use in the study (clopidogrel and prasugrel and ticlopidine, inclusive), everolimus, poly (L-lactide), poly (DL-lactide), cobalt, chromium,

nickel, tungsten, acrylic and fluoro polymers or contrast sensitivity that cannot be adequately pre-medicated.
• Subject has a known diagnosis of acute myocardial infarction (AMI) at any time preceding the index procedure and relevant cardiac enzymes (according to local standard hospital practice) have not returned within normal limits at the time of procedure.
• Evidence of ongoing acute myocardial infarction in ECG prior to procedure
• Subject has current unstable arrhythmias.
• Left ventricular ejection fraction (LVEF) < 30%.
• Subject has received a heart transplant or any other organ transplant or is on a waiting list for any organ transplant.
• Subject is receiving or scheduled to receive chemotherapy for malignancy within 30 days prior to or after the procedure.
• Subject is receiving immunosuppressant therapy and/or has known immunosuppressive or autoimmune disease (e.g. human immunodeficiency virus, systemic lupus erythematosus, rheumatoid arthritis, severe asthma requiring immunosuppressive medication, etc.).
• Subject is receiving chronic anticoagulation therapy that can not be stopped and restarted according to local hospital standard procedures.
• Elective surgery is planned within 2 years after the procedure that will require discontinuing either aspirin, clopidogrel, prasugrel or ticlopidine.
• Subject has a platelet count <100,000 cells/mm3 or >700,000 cells/mm3, a WBC of <3,000 cells/mm3, or documented or suspected liver disease (including laboratory evidence of hepatitis)
• Known renal insufficiency (e.g., eGFR <60 ml/kg/m2 or serum creatinine level of >2.5 mg/dL, or subject on dialysis).
• History of bleeding diathesis or coagulopathy or will refuse blood transfusions.
• Subject has had a cerebrovascular accident (CVA) or transient ischemic neurological attack (TIA) within the past 6 months.
• Pregnant or nursing subjects and those who plan pregnancy in the period up to 3 years following index procedure. (Female subjects of child-bearing potential must have a negative pregnancy test done within 28 days prior to the index procedure and contraception must be used during participation in this trial)
• Other medical illness (e.g., cancer or congestive heart failure) or known history of substance abuse (alcohol, cocaine, heroin etc.) as per physician judgment that may cause non-compliance with the protocol or confound the data interpretation or is associated with a limited life expectancy.
• Subject is already participating in another clinical investigation that has not yet reached its primary endpoint.
• Subject is belonging to a vulnerable population (per investigator*s judgment, e.g., subordinate hospital staff or sponsor staff) or subject unable to read or write.;Angiographic Exclusion Criteria
• Target lesion which prevents adequate (residual stenosis at target lesion(s) is <= 40% by visual assessment) coronary pre-dilatation.
• Target lesion in left main trunk.
• Aorto-ostial target lesion (within 3 mm of the aorta junction).
• Target lesion located within 2 mm of the origin of the LAD or LCX.
• Target lesion located distal to a diseased (vessel irregularity per angiogram and >20%

stenosed lesion) arterial or saphenous vein graft.
• Target lesion involving a bifurcation lesion with side branch >=2 mm in diameter, or with a side branch <2mm in diameter requiring protection guide wire or dilatation.
• Total occlusion (TIMI flow 0), prior to wire crossing
• Excessive tortuosity (>= two 45° angles), or extreme angulation (>=90 °) proximal to or within the target lesion.
• Restenotic from previous intervention
• Heavy calcification proximal to or within the target lesion.
• Target lesion involves myocardial bridge.
• Target vessel contains thrombus as indicated in the angiographic images.
• Additionally clinically significant lesion(s) (>= 40% diameter stenosis by visual assessment) for which PCI may be required <2 years after the index procedure.
• Subject has received brachytherapy in any epicardial vessel (including side branches)
• Subject has a high probability that a procedure other than pre-dilatation and study device implantation and (if necessary) post-dilatation will be required at the time of index procedure for treatment of the target vessel (e.g. atherectomy, cutting balloon)

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):	17-01-2012
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	scaffold
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-12-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-11-2012
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	01-12-2013
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2014
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	NL37001.078.11