ABSORB PHYSIOLOGY Clinical Investigation: Clinical Evaluation of the Short and Long-Term Effects of the Abbott Vascular Everolimus-Eluting Bioresorbable Vascular Scaffold on Coronary Artery Blood Flow and Physiological Responsiveness

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

Summary

ID

NL-OMON35248

Source
ToetsingOnline

Brief title
ABSORB PHYSIOLOGY

Condition

- Coronary artery disorders

Synonym
coronary artery disease, Coronary heart disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Bioresorblable scaffold, Coronary sclerosis, PCI

Outcome measures

Primary outcome

Primary Outcome Measures

Coronary Artery Endothelial Responsiveness to:

- Flow-mediated dilation (FMD) induced by pacing and hand-grip

- Direct (intra-coronary) infusion of acetylcholine

Clinical Outcomes

Standard percutaneous coronary intervention (PCI)-type clinical outcomes will

be captured (Refer to Section 4.4.2 for details).

Secondary outcome

Secondary Outcome Measures

Coronary artery cross-sectional compliance and cross-sectional distensibility.

Study description

Background summary

The ABSORB PHYSIOLOGY Clinical Investigation is a prospective, randomized study comparing the coronary artery blood flow and physiological responsiveness of

the target artery between participants implanted with an Abbott Vascular Everolimus-Eluting Bioresorbable Vascular Scaffold (BVS) or a traditional metallic drug-eluting stent (mDES) for a single, de novo native coronary artery lesion.

After the resorption of the Bioresorbable Vascular Scaffold (BVS), there will be a return towards a physiological-like behavior of the previously stented/scaffolded segment and a greater likelihood that the target artery may be able to accommodate increased coronary blood flow in comparison to traditional mDES by showing an improved response to endothelial flow related response. In contrast, this hypothesized benefit of a bioresorbable scaffold will not occur in arterial segments stented with a rigid metal stent that persists.

ABSORB PHYSIOLOGY will evaluate the short and long-term effects of an implanted BVS or mDES on coronary artery blood flow and physiological responsiveness of the target artery to test the hypothesis.

Study objective

The objective of the ABSORB PHYSIOLOGY is to evaluate the following in participants undergoing coronary artery scaffolding/stenting for significant coronary artery disease:

• The acute (post-implantation) effect of an implanted BVS or mDES on coronary blood flow and physiological responsiveness of the target coronary artery

• The long-term (2 years) effect of an implanted BVS or mDES on coronary blood flow and physiological responsiveness of the target coronary artery

Study design

ABSORB PHYSIOLOGY is a prospective, randomized, single-blinded, multi-center clinical investigation that will enroll a minimum of 36 participants at 6 to 8 sites. Participants with a single, de novo native coronary lesion suitable to be treated with either a BVS or an mDES and having an additional angiographically smooth (< 40% diameter stenosis) control vessel will be enrolled. Participants will be randomized 2:1 to BVS or mDES treatment. The BVS arm will enroll a minimum of 24 participants and the mDES arm will enroll a minimum of 12 participants.

Physiology studies evaluating physiological responsiveness of the coronary artery and coronary blood flow will be performed in both the target vessel and the control vessel for all participants following the PCI procedure (baseline) and at 2 years. The angiographically smooth, nonintervened control vessel will be used as an intra-participant control (self-control vessel) to eliminate

potential medical treatment/disease progression effects. Comparisons will be made between the target vessel and the self-control vessel within participants and between participants undergoing BVS or mDES treatment, as well as across different time points.

Intervention

Placement of the scaffold will not differ from a routine stent procedure. Post-placement of the scaffold includes IVUS, OCT and physiological tests. Apart from twice a telephone follow-up (or outpatients), an additional angio will be done at 2 years , including IVUS, OCT and physiological tests.

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
1831 Diegem
BE
Scientific
Abbott Vascular International

Park Lane, Culliganlaan 2B
1831 Diegem
BE

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Most important General Inclusion Criteria
-Participant must have evidence of myocardial ischemia (e.g., stable or unstable angina, silent ischemia with a positive functional study).
-Participant must be an acceptable candidate for coronary artery bypass graft (CABG) surgery.;Angiographic Inclusion Criteria
1. A single de novo native coronary artery lesion suitable to be treated by either a BVS or a mDES.
2. Target lesion must be located in a native coronary artery in which the mean proximal and distal vessel diameter of the target lesion (Dmean) fall within the range of >= 2.25 mm and <= 3.25 mm and the target lesion length measures <= 22 mm as assessed by IVUS.
3. Target lesion must be located in the main branch of a major epicardial vessel (i.e., LAD, LCX, or RCA) with a visually estimated diameter stenosis of >= 50% and < 100% with a TIMI flow of >= 1.
4. Participant must have an additional angiographically smooth (< 40% diameter stenosis) non-target vessel to act as an intra-participant control vessel (self-control vessel). The self-control vessel must be the main branch of a major epicardial vessel (i.e., LAD, LCX, or RCA).
5. Coronary anatomy must be suitable for IVUS, OCT, and pressure and flow wire instrumentation.

Exclusion criteria

Most important general exclusion criteria
1. Participant has a known diagnosis of spontaneous acute myocardial infarction (AMI) within 14 days preceding the index procedure.
2. Participant has high-risk acute coronary syndrome (e.g., dynamic ST-T wave change on ECG or recurrent chest pain/nitrate-unresponsive prolonged chest pain at rest within 48 hours prior to the index procedure).

3. Participant has any evidence of myocardial infarct in the territory subtended by the proposed target vessel or self-control vessel.
4. Participant has current unstable arrhythmias.
5. Participant has chronic atrial fibrillation.
6. Participant has a known left ventricular ejection fraction (LVEF) < 40%.
7. Participant has received a heart transplant or any other organ transplant or is on a waiting list for any organ transplant.
8. Participant has previously had CABG or mitral or aortic valve repair/replacement.

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):	01-10-2011
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Coronary stent
Registration:	No

Ethics review

Approved WMO

Date:	22-12-2011

Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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
ClinicalTrials.gov	NCT01308346
CCMO	NL37887.101.11