Axetis Inert Coronary Stent System First in Man (FIM) Clinical Investigation

Published: 18-12-2013
Last updated: 24-04-2024

The objective is to assess the feasibility and safety of the Axetis Inert Stent for treatment of patients with de novo coronary artery stenosis in native vessels.

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

Summary

ID

NL-OMON40619

Source
ToetsingOnline

Brief title
AXETIS FIM

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, coronary artery stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Axetis AG
Source(s) of monetary or material Support: Sponsor (Axetis AG)

Intervention

Keyword: Clinical Investigation, First in Man, Inert Coronary Stent System, Inert SiOx surface

Outcome measures

Primary outcome

The primary endpoint is in-stent Late Lumen Loss (LLL) at 6 months after stent implantation as assessed by off-line QCA.

Secondary outcome

Angiographic endpoints:

* Acute Lumen Gain (mm);

* MLD (mm) post procedure and at 6 months;

* Diameter Stenosis (%) post procedure and at 6 months;

* Binary Restenosis (DS *50%) at 6 months

All measurements will be made of the in-stent, in-segment, proximal and distal stent margins

OCT endpoints

Quantitative assessment at baseline

* prolapse area/volume

Quantitative assessment (at baseline and at 6 months follow-up):

* Mean/Minimal Lumen diameter/area/volume

* Mean/Minimal Stent diameter/area/volume

* Incomplete strut apposition

Quantitative assessment (at 6 months follow-up):

* In-stent neointimal hyperplasia volume obstruction (%)

* Neointimal hyperplasia area/volume

* Mean/maximal thickness of the struts coverage

* Percentage number of covered struts

Quantitative and Qualitative assessment:

* Residual edge dissections

* Thrombus (intraluminal mass)

Clinical endpoints:

* Acute success (device and procedural success)

* Device-oriented Composite Endpoints at 6 months and 12 months

(Device-oriented Composite Endpoint (DoCE) is defined as Cardiac Death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated TargetLesionRevascularization) and its individual components.

* Stent thrombosis according to the ARC definitions up to 12 months follow-up.

Study description

Background summary

One or two of the patients' coronary arteries has a significant narrowing that is causing decreased blood flow to your heart muscle. To prevent damage to the heart muscle, this narrowing has to be resolved. This is commonly done with a percutaneous coronary intervention (PCI). The procedure is performed by entering the arteries with a catheter trough your groin or arm. By X-ray, the coronary arteries are made visible. A balloon and then a stent are placed within the narrowing in the artery to achieve the desired result; a reopened artery with good blood flow.

Stent placement means that a small metal scaffold (stent) is left behind after the balloon is removed and the stent becomes a permanent part of the artery. Stents have been used for many years to treat narrowing of both coronary arteries and bypass grafts (saphenous vein grafts). The Axetis Inert Stent is a standard stent with a special surface treatment which have shown in pre-clinical studies significant reduction of restenosis or re-narrowing of the artery after the treatment. The procedure itself is a standard procedure for this condition.

Study objective

The objective is to assess the feasibility and safety of the Axetis Inert Stent for treatment of patients with de novo coronary artery stenosis in native vessels.

Study design

Prospective, multicentre, open-label and single arm study, conducted in 2 to 3 interventional cardiology centers in The Netherlands. In total, approximately 35 patients will be enrolled. All patients will be treated with Axetis Inert Coronary Stent System

Clinical follow-up will occur at 6 and 12 months post-stent implantation. All patients will undergo repeat angiography at 6 months follow-up. QCA assessment will be performed at baseline (pre- and post-procedure) and at 6 months follow-up.
All patients will undergo Optical Coherence Tomography (OCT) investigation at baseline (post procedure) and at 6 months follow-up.

Off-line QCA and OCT analysis will be performed by an independent core laboratory (Cardialysis BV, Rotterdam, The Netherlands) according to pre-set Standard Operating Procedures.

Clinical data will be adjudicated by an independent Clinical Event Committee.

Intervention

Axetis Inert Stent

Study burden and risks

Potential Risks
The coating on the stent is tested in depth and the materials used are well known, there is little potential to cause side effects. Long term animal studies performed showed the stent does not have toxic or damaging effects on the body. However, if the patient experiences any signs of an allergic reaction

such as rash, itching or swelling, he/she should inform the study team (cardiology department) immediately. Previous stent implantation studies involving the use of antiplatelet have shown a 1 to 2 % chance of blood clotting within the stent.

This treatment may involve some additional risks to the patient, the nature of which is unknown. Potential risks in case of pregnancy are not known for this treatment and the use of adequate birth control during the course of the study is mandatory for women in their fertile period.

Potential complications and adverse effects due to the use of this stent are the same to any routinely performed coronary stenting procedure and therapy.

Potential Benefits
The Axetis Inert stent, a Bare Metal Stent with a special surface treatment, and has shown very promising results in pre-clinical studies. It shows an important lowering of restenosis or re-narrowing of the artery after the treatment compared to conventional Bare Metal Stents. In addition, the Axetis Inert Stent has also shown to become completely part of the inner lining of the artery, reducing the risk for late stent thrombosis.

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

*18 to 85 years
*Evidence of myocardial ischemia without elevated Troponin / cardiac biomarkers (e.g. stable or unstable angina, silent ischemia demonstrated by positive territorial functional study). NSTEMI patients are allowed, as long as Troponin is within the normal limits before the start of the procedure.
*The patient has a planned intervention of up to two de-novo lesions in two different vessels (previously untreated vessels)
*Lesion must have a visually estimated diameter stenosis of *50% and <100%.
*Lesion length must be * 28 mm
*RVD must be between 2.4 and 3.8 mm
*Written informed consent
*The patient and the patient*s physician agree to the follow-up visits including angiographic follow-up and OCT control at 6 months

Exclusion criteria

- Evidence of ongoing acute myocardial infarction in ECG and or elevated cardiac biomarkers prior to procedure
- LVEF <30%
- Platelet count <100,000 cells/mm3 or >400,000 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
- The patient is a recipient of a heart transplant
- Known hypersensitivity or contraindication to aspirin, heparin, antiplatelet medication specified for use in the study (clopidogrel, prasugrel, ticagrelor and ticlopidine) or stainless steel
- Other medical illness (e.g. cancer, stroke with neurological deficiency) 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
- Pregnant or breastfeeding woman or woman in fertile period not taking adequate contraceptives
*Severe tortuous, calcified or angulated coronary anatomy of the study vessel that in the

opinion of the investigator would result in suboptimal imaging or excessive risk of complication from placement of an OCT catheter
*Target lesion in left main stem.
*Target lesion involves a side branch > 2.0mm in diameter
*Aorto-ostial target lesion (within 3 mm of the aorta junction).
*Total occlusion or TIMI flow 1, prior to wire crossing
*The target vessel contains visible thrombus
*Restenotic lesion
*Located within an arterial or saphenous vein graft
*Target vessel with previously placed stent or with graft
*Treatment of more than 1 lesion in one vessel, or treatment of more than two lesions

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2014
Enrollment:	35
Type:	Actual

Medical products/devices used

Generic name:	Axetis Inert Coronary Stent System
Registration:	No

Ethics review

Approved WMO

Date:	18-12-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL44586.018.13