Qvanteq Bioactive Coronary Stent System First in Man (FIM) Clinical Investigation

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The objective is to assess the feasibility and safety of the Qvanteq*s bioactive coronary Qstent for treatment of stable coronary artery disease 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-OMON40746

Source
ToetsingOnline

Brief title
QUEST I

Condition

- Coronary artery disorders

Synonym
myocardial ischemia and coronary atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: QVANTEQ
Source(s) of monetary or material Support: Qvanteq AG

Intervention

Keyword: Bioactive, Lumen, Neointimal, Stent

Outcome measures

Primary outcome

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

The primary OCT endpoint is mean neointimal thickness as assessed by OCT at 6 months by off-line OCT analysis.

Secondary outcome

Angiographic endpoints:

• Acute Lumen Gain (mm);

• In-segment Late Lumen Loss (LLL) at 6 months;

• 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

• Stent symmetry

• Stent expansion

• 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

• Percentage of incomplete apposed struts

• Healing Score

Quantitative and Qualitative assessment:

• Residual edge dissections

• Thrombus (intraluminal mass)

Clinical endpoints:

• Acute success (device and procedural success)

• Device-oriented Composite Endpoints at 1, 6 and 12 months and its individual components (Device-oriented Composite Endpoint (DoCE) is defined as Cardiac Death, MI not clearly attributable to a non-intervention vessel, and

clinically-indicated Target Lesion Revascularization).

• Death at all timepoints

• Myocardial infarction (Q-wave, Non q-wave) at all timepoints

• Revascularization of the target vessel, clinically indicated at all timepoints

• Any revascularization at all timepoints

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

Study description

Background summary

The introduction of newer generation DES have improved both the safety and efficacy compared to BMS and early generation DES. Nevertheless, the risk of late stent thrombosis and the associated need for prolonged dual antiplatelet therapy remains an important clinical caveat. European and American society of cardiology recommend a DAPT duration of 1 year following implantation of DES in view of an increased risk of stent thrombosis mainly observed in observational (all comers) studies. Reasons for an increased risk of stent thrombosis following DES implantation are mainly the impaired healing of DES with a delay in endothelialisation and an increased inflammatory response (granuloma formation). Whilst the shortening of DAPT may carry the risk of an increased risk of stent thrombosis following DES implantation, any prolongation of DAPT goes along with an increased bleeding risk.

An ideal situation would be achieved with a stent device, which shows optimal healing properties, specifically a fast endothelialisation (similar to BMS), a low degree of inflammation and a sustained efficacy based on a minimal neointimal proliferation (comparable to DES). Such a device by definition would not require a prolonged DAPT throughout one year (similar to a BMS) and thereby limit the bleeding risk. Particularly for patients with an increased bleeding risk or for patients requiring oral anticoagulation (triple therapy, approximately in 8% of patients undergoing PCI), the avoidance of a DAPT for more than 1-3 months would be beneficial to decrease the risk for DAPT induced bleeding.

The Qstent is a Cobalt Chromium stent which underwent Qvanteq*s proprietary surface treatment. The development goal for Qvanteq*s surface treated Qstent is to achieve a fast endothelial growth (similar to a BMS), which however is not resulting in an excessive neointimal hyperplasia as observed in BMS but rather

has an efficacy profile similar to DES. This should reduce the risk of restenosis and thrombus formation despite the presence of a short term DAPT. Both in-vitro and in-vivo studies have shown positive promising results with Qvanteq*s surface treated stents regarding this.

Study objective

The objective is to assess the feasibility and safety of the Qvanteq*s bioactive coronary Qstent for treatment of stable coronary artery disease patients with de novo coronary artery stenosis in native vessels.

Study design

Prospective, multicentre, open-label and single arm study, conducted in approximately 5 interventional cardiology centers in Switzerland and the Netherlands. In total, approximately 35 patients will be enrolled. All patients will be treated with the Qstent (bioactive stent, Qvanteq AG, Zurich, Switzerland).

Clinical follow-up will occur at 1, 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, documentary) and at 6 months follow-up. At baseline, the OCT should be performed after the successfully completed angiographic procedure (i.e. angiography guided Qstent implantation).

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.

An independent Data Safety Monitoring Board (DSMB) will monitor the individual and collective safety of the patients in the study on an ongoing basis.

Intervention

The patient has a planned intervention of one single de novo lesion in one or two separate major epicardial territories (LAD, LCX, or RCA).

Study burden and risks

The potential risks are the well-known and common risks associated with any PCI. Potential complications and adverse effects due to the use of this stent

include, but are not limited to death, stroke/cerebrovascular accidents, myocardial infarction, stent thrombosis or occlusion of the coronary artery that was treated, or another coronary artery, need for emergent coronary artery bypass grafting (CABG) or percutaneous coronary intervention (PCI), procedural adverse events, such as coronary spasm with myocardial ischemia, perforation or cardiac tamponade, or dissection, distal embolization (air, tissue or thrombotic emboli), side branch compromise, bleeding complications, access vascular complications, such as hematoma, hemorrhage requiring transfusion, pseudoaneurysm, peripheral ischemia, peripheral nerve injury, infection and pain at the insertion site, arrhythmias, including ventricular fibrillation or ventricular tachycardia, hypotension/Hypertension, allergic reaction to drugs/contrast medium/stent material.

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

• Subjects must be at least 18 years of age
• Evidence of myocardial ischemia without elevated cardiac biomarkers (e.g. stable or unstable angina with stable haemodynamic condition, or silent ischemia demonstrated by positive territorial functional study)
• The patient has a planned intervention of one single de novo lesion in one or two separate major epicardial territories (LAD, LCX, or RCA)
• Lesion must have a visually estimated diameter stenosis of >=50% and <100%
• Lesion length must be <=16 mm
• Vessel size must be between 2.5 mm and 3.5 mm
• Written informed consent
• The patient agrees to the follow-up visits including angiographic follow-up and OCT control at 6 months

Exclusion criteria

• Evidence of ongoing acute myocardial infarction (AMI) in ECG and/or elevated cardiac biomarkers (according to local standard hospital practice) have not returned within normal limits at the time of procedure.
• Patient suffered from stroke/TIA or myocardial infarction during the last 6 months
• Left ventricle ejection fraction (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, or subject on dialysis, or acute kidney failure.
• Patient undergoing planned surgery within 6 months with the necessity to stop ASA
• Patient requiring prolonged DAPT for other diagnoses (>1 month)
• History of bleeding diathesis or coagulopathy
• Patient requiring oral anticoagulation (Coumadin, NOAC)
• The patient is a recipient of a heart transplant
• Known hypersensitivity or contraindication to aspirin, heparin, clopidogrel or cobalt-chromium
• 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
• Female of child bearing potential (age <50 years and last menstruation within the last 12 months), who did not underwent tubal ligation, ovariectomy or hysterectomy.

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):	19-12-2014
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	bioactive stent
Registration:	No

Ethics review

Approved WMO

Date:	29-10-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	22-07-2015
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	NL48848.078.14