Prospective, multi-center, randomized First-In-Man trial to compare the safety and efficacy of BuMA Supreme eG (Electro Grafting) based biodegradable polymer Sirolimus-eluting stent against Resolute Zotarolimus-eluting durable polymer stent in patients with de novo coronary artery lesions.

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To evaluate the safety and effectiveness of the SINOMED BuMA Supreme Sirolimus-Eluting Coronary Stent System with biodegradable polymer versus the Medtronic Resolute Zotarolimus-Eluting Coronary Stent System through angiographic and clinical...

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

Summary

ID

NL-OMON42177

Source
ToetsingOnline

Brief title
PIONEER

Condition

- Coronary artery disorders

Synonym
Coronary artery disease, Coronary artery stenosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Biodegradable polymer Sirolimus-eluting stent, BuMA Supreme eG, Coronary artery lesions, First-In-Man

Outcome measures

Primary outcome

In-stent Late Lumen Loss (LLL) at 9 months after stent implantation as assessed

by off-line QCA.

Secondary outcome

Angiographic endpoints:

* Acute Lumen Gain (mm);

* In-segment LLL (mm) at 9 months;

* MLD (mm) post procedure and at 9 months;

* Diameter Stenosis (%) post procedure and at 9 months;

* Binary Restenosis (DS *50%) at 9 months.

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

stent margins.

Clinical endpoints:

* Acute success (device and procedural success);

* Device-oriented Composite Endpoints (DoCE) at 1, 9, 12, 24 and 36 months and its individual components. (Device-oriented Composite Endpoint is defined as Cardiac Death, MI not clearly attributable to a non-intervention vessel, and clinically-indicated Target Lesion Revascularization);

* Death at all time points;

* Myocardial infarction (Q-wave, Non q-wave) at all time points;

* Revascularization of the target vessel, clinically indicated at all time points;

* Any revascularization at all time points;

* Stent thrombosis according to the ARC definitions up to 36 months follow-up.

Study description

Background summary

One of the patient's coronary arteries has a significant narrowing that is causing decreased blood flow to the 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 through the 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. There are simple metal stents and drug eluting stents (DES). In this trial drug eluting stents are used, which gives a reduction of restenosis or re-narrowing of the artery. The procedure itself is a standard procedure for this condition.

Study objective

To evaluate the safety and effectiveness of the SINOMED BuMA Supreme

Sirolimus-Eluting Coronary Stent System with biodegradable polymer versus the Medtronic Resolute Zotarolimus-Eluting Coronary Stent System through angiographic and clinical endpoints.

Study design

Prospective, multi-center, randomized 1:1, single blind trial using BuMA Supreme versus Resolute conducted in approximately 12-14 interventional cardiology centers in The Netherlands, Belgium, Spain and Portugal. Clinical follow-up will occur at 1, 9, 12, 24 and 36 months post-stent implantation. All patients will undergo repeat angiography at 9 months follow-up. QCA assessment will be performed at baseline (pre- and post-procedure) and at 9 months follow-up.

Intervention

BuMA Surpreme stent or Resolute stent

Study burden and risks

Burden:
The patient needs to visit the hospital a few times for additional visits which will take extra time.

Risks:
The amount of Zotarolimus released by the Resolute stent and the amount of Sirolimus released by the BuMA Surpreme stent is a very small percentage of the dose given orally for months or even years for treatment of other diseases. This treatment may involve some additional risks to the patient, the nature of which are unknown. Potential risk in case of pregnancy are not known for this treatment, therefore the use of adequate birth control during the course of the trial 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. These can be: death, stroke, heart attack, renarrowing of the coronary artery or another coronary artery, necessity of bypass surgery or rePCI.

Benefits:
A potental benefit is that animal studies suggest that the BuMA stent could be associated with a better early endothelialization due to an ultra thin base layer. The PIONEER trial is designed to assess the safety and efficacy of the BuMA Supreme stent in comparison with the Resolute zotarolimus eluting stent. Participation of the trial might not have a direct benefit, but it will contribute to the valuable knowledge of researchers and physicians for treatment of future patients with the same condition. The medical condition of

the patient is closely monitored during the trial.

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

1. At least 18 years of age.
2. Clinical evidence of ischemic heart disease and/or a positive territorial functional study.
3. Clinical evidence of myocardial ischemia and/or a positive territorial functional study. Stable angina pectoris (Canadian Cardiovascular Society (CCS) Classification 1, 2, 3 or 4) or unstable angina pectoris (Braunwald Class IB-C, IIB-C, or IIIB-C), or silent ischemia
4. The patient has a planned intervention of a single de-novo lesion in one or two separate major epicardial territories (LAD, LCX or RCA).
5. Diameter Stenosis *50 and *100%.
6. The visually estimated target lesion must be able to be covered by a single BuMA Supreme

stent or a single Resolute stent (for available sizes refer to table x, page x).
7. The target lesion reference diameter must be visually estimated to be *2.5 mm and *4.5 mm in diameter.
8. Written informed consent.
9. The patient agrees to the follow-up visits including a 9 month angiographic follow-up.
10. Patient must have completed the follow-up phase of any previous study.

Exclusion criteria

1. Female of child bearing potential (age <50 years and last menstruation within the last 12 months). Subjects with age <50 who underwent tubal ligation, ovariectomy or hysterectomy can be included.
2. 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
3. Patient suffered from stroke/TIA during the last 6 months.
4. LVEF <30%
5. 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)
6. Known renal insufficiency (e.g. serum creatinine >2.5mg/dL, or creatinine clearance *30 mL/min), or subject on dialysis, or acute kidney failure (as per physician judgment).
7. Patient undergoing planned surgery within 6 months with the necessity to stop DAPT.
8. Patient requiring oral anticoagulation (Coumadin, Novel Oral Anticoagulant (NOAC))
9. History of bleeding diathesis or coagulopathy
10. The patient is a recipient of a heart transplant
11. Known hypersensitivity or contraindication to aspirin, heparin, antiplatelet medication specified for use in the study, sirolimus, zotarolimus, or cobalt-chromium.
12. 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
13. The patient is simultaneously participating in another investigational device or drug study.
Angiographic Exclusion criteria
The following angiographic exclusion criteria are applied:
1. Target lesion in left main stem.
2. Target lesion involves a side branch >2.0mm in diameter
3. Aorto-ostial target lesion (within 3 mm of the aorta junction).
4. Total occlusion or TIMI flow <2, prior to wire crossing
5. The target vessel contains visible thrombus
6. Restenotic lesion.
7. The lesion is located within an arterial or saphenous vein graft or distal to a diseased arterial or saphenous vein graft

Study design

Design

Study phase:	2
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):	24-04-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	BuMA Supreme Sirolimus-eluting stent
Registration:	No

Ethics review

Approved WMO Date:	05-02-2015
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-07-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	03-09-2015

Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-10-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	NCT02236975
CCMO	NL50420.044.14