A Prospective, Active control, open label, Multicentre Randomized Clinical Trial for comparison between BioMime Sirolimus Eluting Stent, or Meril Life Sciences and Xience Everolimus Eluting stent or Family of Abbott Vascular Inc.. to Evaluate Efficacy and Safety in Coronary Artery Disease

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To Evaluate the safety and efficacy of the sirolimus-eluting stent system BioMime Compared to the Abbott's XIENCE (V Xpedition or Prime) Everolimus-eluting stent system in the treatment of patients with up to two de novo native coronary artery...

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

Summary

ID

NL-OMON41944

Source
ToetsingOnline

Brief title
Merit - V

Condition

- Coronary artery disorders

Synonym
Heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Meril Life Sciences Pvt. Ltd.
Source(s) of monetary or material Support: Medical Device Industry

Intervention

Keyword: BioMime, Eluting, Sirolimus, Stent

Outcome measures

Primary outcome

Primary Endpoint:

The primary endpoint of this study is to assess in-stent Late Lumen Loss at 9 months for both treatment strategies. Late lumen loss is defined as the difference in minimal luminal diameter (MLD) between post-procedural and follow up MLD in mm.

The Analysis of primary endpoints is performed on basis of the evaluation of the angiography images by an independent core laboratory.

Secondary outcome

Secondary Endpoints:

Angiographic endpoints

- In Stent and In segment Binary Restenosis (DS >=50%) at 9 months

- In Stent and In segment MLD and %DS post procedure at 9 months

- In-segment Late Lumen Loss 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)

* Major Adverse Cardiac Events (MACE) at 1, 5, 9,12 and 24 months and its individual components. defined as cardiac death, MI and clinically-indicated target Vessel revascularization)

* Target Vessel Failure at 1, 5, 9, 12 and 24 months and its individual components. defined as cardiac death, MI not clearly attributable to a non-intervention vessel and clinically-indicated target Vessel revascularization)

* Device-oriented Composite Endpoints at 1, 5, 9, 12 and 24 months and its individual components. (Device-oriented Composite Endpoint (DoCE) is defined as cardiac death or MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularization)

* Non clinically-indicated (Asymptomatic but detected by follow-up angiography) Target Lesion revascularization (TLR) at 1, 5, 9, 12 and 24 months

* Clinically-indicated (Due to clinical Features of Ischemia) and non clinically-indicated(Asymptomatic but detected by follow-up angiography) Target Vessel revascularization (TVR) at 1, 5, 9, 12 and 24 months

* Stent Thrombosis - according to ARC definitions at all time points

Study description

Background summary

While drug eluting stents of the present generation the threat of restenosis, which is the safety concern of stent thrombosis is still there. The newer devices with newer drugs and bio-compatible polymers better results, particularly small stent thrombosis in comparison to the first generation of stents demonstrated. However, there is still room for improvement. Major changes were the use of biodegradable polymers as carriers for the DES instead of solid polymers and reduced strut thickness. Have the risk of stent thrombosis is reduced to 56% these changes. This changereduced the risk of stent thrombosis and gradually with more developments; DES angioplasty was accepted for a broader population, which was regarded as the domain of the operation earlier. The successes of biodegradable polymers in reducing stent thrombosis rate and overall outcome was demonstrated by LEADERS, paint and MERIT-1 studies. Several Drug eluting stents are now being introduced with biodegradable polymers. Most of the clinical studies, the clinical performance of the stent as a result of a number of long and large population of observations. Most of these studies were carried out in a simpler population. Hence, the practical clinical application of day-to-day practice complex group of patients treated with DES was very less relevant. Most of these studies also demonstrated that the effective mechanical properties of the stent, especially thinner
struts, are responsible for the low binary restenosis and late loss low. Eventually, the smaller population surrogate endpoints in clinical trials of stent were considered for efficacy reasons.

Study objective

To Evaluate the safety and efficacy of the sirolimus-eluting stent system BioMime Compared to the Abbott's XIENCE (V Xpedition or Prime) Everolimus-eluting stent system in the treatment of patients with up to two de novo native coronary artery lesions through clinical and angiographic endpoints.

Study design

A prospective, open label, active controlled, 2:1 randomized, interventional clinical trial, with surrogate endpoints and clinical evaluation.

Intervention

Patients who suffer from coronary artery disease will undergo angiography and Angioplasty procedure.

Study burden and risks

There are a number of possibilities, but unusual discomforts and risks of your disease, angioplasty and the use of the stent. Most of these conditions are as rare as one in 10,000. These risks are potentially the same in this study. The amount of drug on the stent is very low. However, such potential side effects have also been associated with the daily oral administration of sirolimus. A pair of common disorders such as restenosis, stent thrombosis and myocardial infarction observed up to less than 10 percent in previous

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

Inclusion criteria:
* The subjects must be >= 18 years of age.
* Clinical evidence of ischemic heart disease and / or a positive territorial functional study.

- Documented stable angina (Canadian Cardiovascular Society (CCS) Classification 1, 2, 3 or 4)
or
- Documented unstable angina with documented ischemia (Braunwald Class IB-C, C-IIB, IIIB or C),
or
- Documented silent ischemia
* The subject having a planned intervention or up to two de novo native lesions
* Target lesion reference diameter >= 2.5 mm and <= 3.5 mm (visually estimated)
* The target lesion length is less than or equal to 46 mm (visually estimated)
* Subjects willing to providence written informed consent.
* Female subjects without childbearing potential who have either undergone surgical sterilization or is postmenopausal.
* The subject and the subject's physician agree to the follow-up visits-including a 9 month angiographic followup.

Exclusion criteria

Exclusion criteria:
* Evidence of an acute Q-wave or non-Q-wave myocardial infarction within 72 hours Preceding the index procedure, Unless the CK and CK-MB enzymes are less than twice the Upper Limit Normal.
* The subjects who have a known hypersensitivity or contraindication to any of the requisite medications including aspirin, heparin, clopidogrel, prasugrel, ticagrelor, sirolimus, everolimus or the contrast media
* There is an untreated significant lesion or> 40% diameter stenosis proximal or distal to the remaining target site after the planned intervention.
* Previous PCI with stent placement or any at the target lesion and / or within 10 mm of the target lesion.
* Lesion with a significant side branch (branch diameter > 2 mm) thatwould be covered by Stenting
* Total occlusion or coronary TIMI 0 flow in the target vessel.
* Left main coronary artery disease.
* The proximal target vessel or target lesion is severely calcified by visual assessment. aorto-ostial * location, unprotected left main lesion location, or a lesion within 5 mm of the origin of the LAD or LCX.
* The subject has a history of bleeding diathesis or coagulopathy or will refuse blood transfusions
* The subject Suffered a stroke, transient ischemic neurological attack (TIA) or significant gastrointestinal (GI) bleeds within the past 6 months
* The subject has renal insufficiency as Determined by a creatinine of> 2mg/dl or 180 mg / dl.
* The target lesion, or the target vessel proximal to the target lesion contains thrombus
* Documented left ventricular ejection fraction of <= 30%
* The subject is a recipient of a transplant surgery (Heart, Kidney, Liver etc)

* The patient has extensive peripheral vascular disease That precludes safe 6 French sheath insertion
* Extreme angulations of the vessel at access location (<45 degrees)
* The subject has other medical illness (zoals cancer or congestive heart failure) That May cause the patient to be non-compliant with the protocol, confound the data interpretation or is associated with limited life expectancy (ie less than one year)
* The patient is simultaneously participant participating in another investigational drug or device study.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-05-2015
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Biomime (Sirolimus Eluting Coronary Stent System)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-03-2015

Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-01-2016
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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
ISRCTN	ISRCTN:ISRCTN06697555,NCT:NCT02112981
CCMO	NL50565.075.14