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Prospective clinical trial to compare safety & efficacy of BioMime Sirolimus stent Vs. Xience Everolimus stent by random assignment for treatment of coronary artery disease at multinational centres

Submission date	**Recruitment status**	[X] Prospectively registered
11/03/2014	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/04/2014	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/08/2019	Circulatory System	

Plain English summary of protocol

Background and study aims
Coronary artery disease is among the leading causes of mortality in the world. Over the last few decades, coronary angioplasty has progressively taken over the treatment of coronary arterial stenosis from conventional surgical revascularization by coronary artery bypass graft. The procedure involves the use of a stent which is a short wire-mesh tube acting as a scaffold to help keep an artery open. Angioplasty balloon (drug-coated or plain), bare metal stents and drug eluting stents (DES) are commonly used. The new generation of DES have reduced the risk of restenosis (narrowing of blood vessel) but there are still concerns over thrombosis (blot clot within a blood vessel). In this study we will compare two types of DES: BioMime Sirolimus stent vesus Xience Xpediation stent.

Who can participate?
Participants will be male or female above 18 with coronary artery disease with a maximum of two de novo lesions in the native coronary artery. 258 participants will be recruited in several countries.

What does the study involve?
Participants will be randomly allocated to one of two groups: a study group (172 with BioMime) and a control group (86 Xience Xpediation). All patients will undergo an angiographic follow-up at 9 months and will be followed for a period of 2 years.

What are the possible benefits and risks of participating?
Participation in this study may not lead to any short term benefits for you. However, angioplasty is a standard procedure that will help you recover from your cardiovascular disease. BioMime or Xience Xpediation are premium devices which will be provided to you free or at a subsidised cost. Your angiographic follow-up is one of the benefits and this will monitor how your coronary

arteries are doing after your primary angioplasty procedure. The costs will be paid by the study sponsor. Your health status will be closely monitored if you participate in the study. Insurance cover will be provided to the participants. Should stent block happen, the cost of a repeat procedure, whether angioplasty or coronary artery bypass surgery, will be paid by the study sponsor. The scientific data generated about the devices and the disease will help doctors and sponsors to improve the standard of care for people who have a similar condition.
There are some potential but unusual discomforts and risks related to your disease, the angioplasty procedure and the use of a stent. These risks are potentially the same in this study but rare (one in 10,000 people). More common risks (restenosis, stent thrombosis and myocardial Infarction) are less than 10 percent in previous studies.

Where is the study run from?
8-10 centres in Europe and Brazil. Europe: 6-8 centres for 198 participants. Brazil: 2 centres for 60 participants.

When is study starting and how long is it expected to run for?
It is anticipated that recruitment will start April 2014. Participants will be enrolled for a period of two years. However, the study will extend beyond April 2016 as we intend to monitor participants health over many years.

Who is funding the study?
Meril Life Sciences Pvt. Ltd.

Who is the main contact?
Dr. Ashish Indani
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
2013-005353-67

IRAS number

ClinicalTrials.gov number

NCT02112981

Secondary identifying numbers
BioM/RCT/12/03

Study information

Scientific Title
A prospective, active control open label, multicentre randomized clinical trial for comparison between BioMime Sirolimus Eluting Stent of Meril Life Sciences Pvt.Ltd. and Xience Xpedition Everolimus Eluting stent of Abbott Vascular Inc. to evaluate efficacy and safety in Coronary Artery Disease

Acronym
meriT-V

Study objectives
BioMime Sirolimus Eluting stent is better than Xience Xpedition Everolimus Eluting stent for coronary artery disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Two year multi centre open label randomized parallel group active control comparator clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
De novo native coronary artery lesions

Interventions

There will be overall 258 subjects (86 in Control arm and 172 in Study arm) after proper screening and obtaining informed consent form. The randomization will be IWRS based 2:1 randomization of the patients. There will be no stratification factors applied to the population. All the subjects will undergo interventional stent Implantation (Angioplasty) as a part of their treatment, it is not added intervention for protocol. However, the stent choice will be by IWRS-based randomization.

Patients will be followed clinically for a period of 2 years. All patients will undergo angiographic follow-up at 9.5 months. All subjects in the study will undergo the clinical follow-up at 30 ± 7 days, 5 months ± 7 days, 12 months ± 7 days and 24 months ± 7 days. QCA assessment will be performed both at baseline and at 9 months after enrolment.

Intervention Type
Procedure/Surgery

Primary outcome measure
To assess in-stent Late Lumen Loss at 9 months for both treatment strategies

Secondary outcome measures
Angiographic endpoints:
1. Binary Restenosis (DS ≥50%) at 9 months
2. MLD and %DS post procedure at 9 months
3. 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:
1. Acute success (Device and Procedural success)
2. 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, MI not clearly attributable to a non-intervention vessel, and clinically-indicated target lesion revascularization)
3. Non clinically-indicated Target Lesion revascularization (TLR) at 1, 5, 9, 12 and 24 months
4. Clinically-indicated and non clinically-indicated Target Vessel revascularization (TVR) at 1, 5, 9, 12 and 24 months

Overall study start date
20/04/2014

Completion date
20/10/2016

Eligibility

Key inclusion criteria
1. The patient must be ≥18 years of age.
2. Clinical evidence of ischemic heart disease and/or a positive territorial functional study. Documented stable angina pectoris (Canadian Cardiovascular Society (CCS) Classification 1, 2, 3 or 4) or unstable angina pectoris with documented ischemia (Braunwald Class IB-C, IIB-C, or IIIB-C), or documented silent ischemia
3. The patient has a planned intervention of up to two de-novo native lesions
4. Target lesion reference diameter ≥ 2.5 mm and ≤ 3.5 mm in diameter (visually estimated)

5.The target lesion length is less than or equal to 46 mm (visually estimated)
6. Patient willing to provide written informed consent.
7. If the patient is a female, she should be without childbearing potential who has undergone surgical sterilization or is post-menopausal.
8. The patient and the patients physician agree to the follow-up visits including a 9 month angiographic follow-up.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
258 subjects

Total final enrolment
256

Key exclusion criteria
1. 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 Normal Limit.
2. The patient has a known hypersensitivity or contraindication to any of the requisite medications including aspirin, heparin, clopidogrel, prasugrel, ticagrelor, sirolimus, everolimus.
3. There is an untreated significant lesion of > 40% diameter stenosis remaining proximal or distal to the target site after the planned intervention.
4. Previous placement of any stent at the target lesion and/or within 10 mm of the target lesion.
5. Lesion with a significant side branch (branch diameter >2 mm) that would be covered by stenting
6. Total occlusion or TIMI 0 coronary flow in the target vessel.
7. Left Main coronary artery disease (stenosis >50%)
8. The proximal target vessel or target lesion is severely calcified by visual assessment.
9. Aorto-ostial location, unprotected left main lesion location, or a lesion within 5 mm of the origin of the LAD or LCX.
10. The patient has a history of bleeding diathesis or coagulopathy or will refuse blood transfusions
11. The patient suffered a stroke, transient ischemic neurological attack (TIA) or significant gastrointestinal (GI) bleed within the past 6 months
12. The patient has renal insufficiency as determined by a creatinine of > 2.0mg/dl or 180 µmol/l.
13. The target lesion, or the target vessel proximal to the target lesion contains thrombus
14. Documented left ventricular ejection fraction of ≤30%
15. The patient is a recipient of a heart transplant
16. The patient has extensive peripheral vascular disease that precludes safe 6 French sheath insertion or extreme angulations of the vessel at accesslocation (< 45 degrees)

17. The patient has other medical illness (i.e., 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 (i.e., less than one year)
18. The patient is simultaneously participating in another investigational device or drug study.

Date of first enrolment
20/04/2014

Date of final enrolment
20/10/2016

Locations

Countries of recruitment
Belgium

Brazil

India

Italy

Latvia

Netherlands

Spain

Switzerland

United Kingdom

Study participating centre
612, Midas, Sahar Plaza
Mumbai
India
400 059

Sponsor information

Organisation
Meril Life Sciences Pvt. Ltd. (India)

Sponsor details
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396 191

Sponsor type
Industry

Website
http://www.merillife.com/

ROR
https://ror.org/04kz28h20

Funder(s)

Funder type
Industry

Funder Name
Meril Life Sciences Pvt. Ltd. (India)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	07/12/2018	07/08/2019	Yes	No