Clinical Trial Details (PDF Generation Date :- Tue, 24 May 2022 07:18:35 GMT)

CTRI Number	CTRI/2017/01/007638 [Registered on: 06/01/2017] - **Trial Registered Prospectively**
Last Modified On	13/09/2019
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Medical Device
Study Design	Single Arm Study
Public Title of Study	To evaluate safety and performance of CREDENCE™ BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System in subjects with de novo native peripheral artery lesions.
Scientific Title of Study	CREDENCE™ BRS – 1: A prospective, open label and multicentric clinical study to evaluate safety and performance of CREDENCE™ BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System in subjects with de novo native peripheral artery lesions.

Secondary IDs if Any

Secondary ID	Identifier
CREDENCE™ BRS – 1/Version 1.0.0_20 April 2016	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

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Source of Monetary or Material Support

Source of Monetary or Material Support
> Meril Life Sciences Pvt. Ltd. Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala, Vapi-396191, Gujarat, India

Primary Sponsor

Primary Sponsor Details	
Name	Meril Life Sciences Pvt Ltd
Address	Survey No.135, 139, Bilakhia House, Muktanand Marg, Chala ,Vapi – 396 191, Gujarat, India
Type of Sponsor	Other [Medical Device Company]

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
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Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Arnejas Institutional Ethics Committee, Nagpur	Approved	10/01/2018	No
Ethics Committee Sri Ganga Ram Hospital, New Delhi	Approved	03/06/2017	No
HCG Multispeciality Ethics Committee, Ahmedabad	Approved	30/12/2017	No
Institutional Ethics Committee, AIMS, New Delhi	Approved	13/06/2017	No
Institutional Ethics Committee, Cardiology Department, G B Pant Hospital, New Delhi	Approved	30/08/2017	No
Institutional Ethics Committee, Care Hospital, Banjarahills	Approved	15/11/2017	No
Institutional Ethics Committee, Datta Meghe Institute of Medical Sciences, Maharashtra	Approved	08/01/2018	No
Institutional Ethics Committee, Geetanjali University, Rajasthan	Approved	26/02/2018	No
Institutional Ethics Committee, Holy Family Hospital, Mumbai	Approved	09/11/2017	No
Institutional Ethics Committee, Human	Approved	02/05/2017	No

Research -Lokmanya Tilak Municipal Medical College, Mumbai, India			
Institutional Ethics Committee, Kokilaben Dhirubhai Ambani Hospital and Medical Research Institute, Mumbai	Approved	23/01/2017	No
Institutional Ethics Committee, Maharaja Agrasen Hospital, Panjabi Bagh, New Delhi, India	Approved	16/11/2016	No
Institutional Ethics Committee, Max Super Specialty Hospital, New Delhi, India	Approved	17/03/2018	No
Institutional Ethics Committee, Poona Medical Research Foundation, Pune, India	Approved	23/09/2016	No
Institutional Review Board, M S Ramaiah Medical College and Hospitals, Banglore, India	Approved	27/04/2017	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	26/09/2016

Health Condition / Problems Studied

Health Type	Condition
Patients	Peripheral vascular disease, unspecified

Intervention / Comparator Agent

Type	Name	Details
Intervention	Credence™ BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System	Credence™ BRS Sirolimus Eluting BioResorbable Peripheral Scaffold System
Comparator Agent	Nil	Nil

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)
Age To	90.00 Year(s)
Gender	Both
Details	1. Subject is ?18 years of age. 2. Subject has been informed of the nature of the study, and has provided written informed consent, approved by the appropriate Institutional Review Board (IRB) of the respective clinical site. 3. Subject is diagnosed as having symptomatic claudication (Rutherford-Becker Clinical Category 1-3). a. For subjects with bilateral lesions, the higher Rutherford-Becker clinical category limb will be considered the target b. If both limbs are of the same Rutherford Becker clinical category, the target extremity will be selected based on investigator discretion. 4. Subject agrees to undergo all protocol-required follow-up examinations and requirements at the investigational site. 5. Female subject of childbearing potential must have had a negative pregnancy test within 14 days before treatment; not be nursing at the time of the study procedure and agree at time of consent to use birth control during participation

	in this trial. 6. Subject has life expectancy > 12 months. 7. Subject is able to take clopidogrel or prasugrel (or ticlopidine, if the subject cannot take clopidogrel or prasugrel) and acetylsalicylic acid (aspirin). 8. Subject must agree not to participate in any other clinical investigation for a period of 5 years following the index procedure. This includes clinical trials of medications and invasive procedures. Questionnaire-based studies, or other studies that are non-invasive and do not require medication are allowed. Angiographic Inclusion Criteria: 1. Reference vessel diameter (RVD) 2.0-10.0 mm measured by an objective measurement such as online Quantitative Vessel Analysis (QVA). 2. Target lesion is ? 50% DS. 3. Target lesion length ? 70 mm. 4. Patent inflow artery free from significant lesion (? 50% DS and < 100% DS) as confirmed by angiography (treatment of the target lesion acceptable after successful treatment of inflow artery lesion). 5. Patent popliteal artery free from significant lesion (? 50% DS) with at least one patent distal outflow artery (anterior tibial, posterior tibial, or peroneal) that provides in-line circulation to the lower leg and foot, as confirmed by angiography.

Exclusion Criteria

Exclusion Criteria	
Details	1. Acute or chronic renal dysfunction (creatinine > 2.5 mg/dl or >176?mol/L). 2. Severe liver impairment as defined by total bilirubin ? 3 mg/dl or two times increase over the normal level of serum glutamic oxaloacetic transaminase (SGOT) or serum glutamic pyruvic transaminase (SGPT). 3. A platelet count 700,000 cells/mm3; a white blood cell count (WBC) 50% DS) lesion located distal to the target lesion. 3. Acute ischemia of the target extremity. 4. Target extremity has been previously treated with any of the following: •Surgical by pass or •Endarterectomy 5. Target vessel has been previously treated with any of the following: stent, laser, atherectomy, surgical bypass, or endarterectomy. 6. Total occlusion (100 % DS) of the ipsilateral inflow artery. 7. Angiographic evidence of thrombus in target vessel. 8. The target lesion requires treatment with a device other than percutaneous transluminal angioplasty (PTA) (e.g. but not limited to, directional atherectomy, excimer laser, rotational atherectomy, brachytherapy, cryoplasty, etc.). 9. Target lesion is within or adjacent to an aneurysm. 10. Subject has angiographic evidence of thromboembolism or atheroembolism from treatment of an ipsilateral iliac lesion, or from crossing or pre-dilating the target lesion. 11. Target lesion has moderate-to-severe calcification with either of the following characteristics: •Circumferential orientation. •Thickness > 2 mm in either radial or longitudinal direction. 12. Subject has an abdominal aortic aneurysm > 3 cm or history of aortic revascularization.

Method of Generating Random Sequence	Other
Method of Concealment	Other

Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
long-term patency outcomes include drug-eluting stents (DES) and drug-coated balloons (DCB) that deliver antirestenotic agents to the vessel wall and self-expanding covered stents or stent-grafts that prevent neointimal in growth at the site of treatment	1 Month,6 Months,12 Months, 2 years,3 years,4 years and 5 years

Secondary Outcome

Outcome	Timepoints
1. Technical success of the stenting procedure.Technical Success is defined as delivery and deployment of the assigned study stent to the target lesion to achieve residual angiographic stenosis no greater than 30% assessed visually 2. Procedural success of the stenting procedure. Procedural Success is defined as technical success with no MAEs noted within 24 hours of the index procedure 3. Clinically-driven TLR Rate.	1 Month,6 Months,12 Months, 2 years,3 years,4 years and 5 years

Target Sample Size	**Total Sample Size=**30 **Sample Size from India=**30 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2
Date of First Enrollment (India)	16/01/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**5 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Open to Recruitment
Publication Details	NA
Brief Summary	Peripheral arterial disease (PAD) is the systemic arteriosclerosis symptomatically affecting between 3% and 7% of the population and up to one in five patients older than 75 years of age. Mortality in patients with intermittent claudication (IC) is up to four times that in the nonclaudicants. Approximately 55% of claudicants may die from heart disease, 10% from a stroke, and 10% from abdominal vascular pathology. Percutaneous intervention (angioplasty and/or stenting) is the suggested treatment of choice in patients with intermittent claudication (IC) or critical limb ischemia (CLI). Despite the high initial technical success rate of femoral percutaneous transluminal angioplasty (PTA), elastic recoil of the vessel wall, extensive intimal dissection, restenosis and due to intimal hyperplasia remains the major limitations of this technique. Although the use of metallic stents has the ability to overcome acute limitations such as elastic recoil and dissection, long-term outcomes may be compromised by the development of neointimal hyperplasia and late restenosis. Several studies reported that excluding CLI, long-term outcomes of primary stent implantation and balloon angioplasty were similar. Then the Self- Expanding Stents were evaluated by Stent Engineering. Self-expanding nitinol stents again improved endovascular treatment of femoropopliteal disease. Old generation balloon-expandable metal stents are no longer used in the femoropopliteal segment as they are susceptible to external compression and longitudinal axis deformation related to restenosis. New

generation, self-expanding stents, manufactured from a nickel-titanium alloy (nitinol), demonstrate elastic and thermal memory properties suitable for the infrainguinal arterial bed. Nitinol stents conform their superior resistance to torsion, flexion, extension, contraction, and compression compared to stainless steel. Radial expansion of nitinol stents occurs with in situ intra-arterial stent heating and 10–20-fold increase in “spring-like” behavior of nitinol was achieved compared with stainless steel alloys, nitinol stents achieve the predefined nominal diameter once deployed without significant foreshortening. Overlap of nitinol stents must be minimized or ideally avoided as it relates to increased risk of fracture and site-specific restenosis. Suboptimal nitinol stent expansion was related to heavily calcified eccentric or ring-like concentric plaques. Finally, self-expandable stent technology demonstrates specific high resistance to deformation.