MeRes * 1 Extend: A Prospective, Multinational, Multicenter, Single arm, Open label, Pilot Clinical Study of MeRes100 Sirolimus Eluting Bioresorbable Vascular Scaffold System in the Treatment of de-novo native Coronary Artery Lesions

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Primary Objective:* Assess the safety and performance of the MeRes100 Sirolimus Eluting Bioresorbable Vascular Scaffold System (BRS) in subjects with de novo native coronary artery lesions as indicated by proportion of population reporting with...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON43330

Source
ToetsingOnline

Brief title
MeRes * 1 Extend

Condition

- Coronary artery disorders

Synonym
Coronary 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 (Meril Life Sciences Pvt. Ltd.;India)

Intervention

Keyword: Coronary Artery Disease, MeRes-1 Extend, MeRes100, Sirolimus Eluting Bioresorbable Vascular Scaffold System

Outcome measures

Primary outcome

Primary Clinical Endpoint:

* Proportion of population reporting with MACE at 6 months from the day of

index procedure.

Primary Safety Endpoint:

* Proportion of population reporting with Ischemia Driven MACE (ID MACE)

reporting at 6 months (180 days) from the day of index procedure.

Secondary outcome

Clinical Endpoints:

* Ischemia Driven MACE (ID MACE) at 1 month, 6 months and 1, 2 and 3 years.

* Ischemia Driven TVF (ID TVF) at 1 month, 6 months and 1, 2 and 3 years.

* Acute success (clinical device and clinical procedure).

* Ischemia Driven Target Lesion Revascularization (ID TLR) at 1 month, 6 month

and 1, 2 and 3 years

* Ischemia Driven Target Vessel Revascularization (ID TVR) at 1 month, 6

months and 1, 2 and 3 years

* Scaffold thrombosis at 1 month, 6 months and 1, 2 and 3 years

Angiographic Endpoints:

* In-scaffold and In-segment acute gain, post procedure.

* Diameter Stenosis (DS) percent at post procedure, 6 months, and 2 years.

* In-scaffold area Late Loss (LL) at 6months and 2 years

* In-segment LL at 6months and 2years.

* In-scaffold area and In-segment % diameter Stenosis post-procedure and at 6months and 2years.

* In-scaffold area and in-segment Angiographic Binary Restenosis (ABR) rate at 6months and 2years

* Aneurysm, thrombus, and persisting dissection at 6months and 2years.

Optical Coherence Tomography (OCT) Endpoints:

* Mean/minimal lumen diameter/area

* Lumen volume

* Mean/minimal scaffold diameter/area

* Scaffold volume

* Strut area

* Incomplete strut apposition

* Residual edge dissections

* Thrombus (intraluminal mass)

At 6 and 36months follow-up (all the above plus the following)

* In-scaffold neointimal hyperplasia volume obstruction (%)

* Neointimal hyperplasia area/volume

* Mean/maximal thickness of the strut coverage

* Percentage number of covered struts

Study description

Background summary

Meres-1 Extend- is a prospective, multicentre, multinational, single arm trial of MeRes100 Bioresorbable Vascular Scaffold in the treatment of de novo native coronary artery disease. The primary clinical endpoint is major adverse cardiac events (MACE) which is a composite of cardiac deaths, myocardial infarction and target lesion revascularization at 6 months. Primary safety endpoint is ischemia-driven MACE at 6 months. Clinical follow-ups are scheduled at 1, 6, 12, 24 and 36 months. Angiographic follow up are scheduled at 6 months and 24 months, optical coherence tomography (OCT) follow-ups are scheduled at 6 and 36 months.

Study objective

Primary Objective:
* Assess the safety and performance of the MeRes100 Sirolimus Eluting Bioresorbable Vascular Scaffold System (BRS) in subjects with de novo native coronary artery lesions as indicated by proportion of population reporting with ischemia driven Major Adverse Cardiac Events (MACE) at 6 months

Secondary Objectives:
* Assess device success of MeRes100 - BRS in Coronary Artery Disease (CAD)
* Evaluate efficacy of MeRes100 - BRS in CAD
* Evaluate proportion of population reporting with MACE and Target Vessel Failure (TVF) during the course of the study
* Evaluate long-term safety of MeRes100 * BRS

Study design

This is a prospective, multinational, multicentre, single arm, open label pilot study.

Intervention

Patients who suffer from coronary artery disease will undergo angiography, Angioplasty and Optical Coherence Tomography(OCT) procedure.

Study burden and risks

There are possibilities of , unusual discomfort and risks associated with your disease , angioplasty procedure and the use of the Scaffolding . Most of these conditions are rare. These risks are potentially the same in this study. The amount drug on the device is very low. However, such potential side effects are related with the daily oral administration sirolimus . A common disorders such as restenosis , Scaffold thrombosis and myocardial infarction are observed .

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

General Inclusion Criteria:
1. Male or female subjects * 18 years of age
2. Subject is able to sign written Informed Consent Form (ICF)
3. Subjects with symptomatic myocardial ischemia, chronic stable angina
4. The patient has planned intervention of a single de novo lesion in native epicardial vessel
5. Subject who is an acceptable candidate for Coronary Artery Bypass Grafting (CABG)
6. Subject is not participating in any other clinical investigation/study and agrees not to participate in any other clinical investigation/study for a period of 3 years following the index procedure.
7. Subject must agree to undergo all clinical investigation plan-required follow-up visits, angiograms and OCT as per protocol.;Angiographic Inclusion Criteria:
1. Subject with maximum two treatable de novo lesions located maximum one per native epicardial vessel located in major artery or branch, with reference vessel diameter between 2.75, 3.00 and 3.5 mm by on line QCA.
2. Target lesion length * 20 mm.
3. Subjects with Lesion(s), with a visually estimated stenosis of * 50% and < 100% with a TIMI flow of * 1.

Exclusion criteria

General Exclusion Criteria:
1. Subjects unable to provide written informed consent.
2. Pregnant or nursing mother and those who plan pregnancy during the clinical investigation (female patients must have a negative pregnancy test done within 7 days prior to the index procedure and effective contraceptive must be used during participation in this clinical investigation).
3. Subjects with known allergy to Poly-L-Lactide (PLLA), Poly-D,L-Lactide (PDLLA), Sirolimus (Rapamycin) or its any analog or derivative, clopidogrel, ticlopidine, prasugrel, contrast media, platinum, ticagrelor and any drug in dual antiplatelet therapy including aspirin, both heparin and bivalirudin.
4. Subject diagnosed with Acute Myocardial Infarction (AMI) within 7 days preceding the index procedure, as indicated by elevated levels of cardiac enzymes and/or ST segment changes in Electro Cardio Gram (ECG).
5. Subject with history of previous revascularization procedures including CABG and Percutaneous Coronary Intervention (PCI).
6. Subject with vascular aneurysms, cardiac arrhythmias, congestive cardiac failure having LVEF < 30%, cardiac tamponade.
7. Recipient of an organ in an organ transplant procedure or is on a waiting list for any organ transplant.
8. Subjects receiving immunosuppression therapy or having known immunosuppressive or autoimmune disease.
9. Subjects with history of stroke, Cerebro Vascular Accident (CVA) or Transient Ischemic

neurological Attack (TIA). Patients with renal insufficiency where creatinine levels are more than 1.3 mg/dl, known aplastic anaemia, chronic liver disease, platelet count <100,000 cells/mm3, a WBC of < 3,000 cells/mm3.
10. Subjects planned for elective surgery within the first 12 months after the procedure that will require discontinuing dual antiplatelet therapy
11. Subject has a history of bleeding diathesis or coagulatory disease, refuses blood transfusion, significant gastrointestinal or urinary bleed within the past 12 months.
12. Subject having extensive peripheral vascular disease that precludes safe 6F sheath insertion.
13. Subject having a history of paradoxical exercise induced vasoconstriction that is consistent with myocardial bridging in the coronary anatomy.
14. Subjects participating in another clinical investigation.
15. Subjects with short life expectancy such as cancer, Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), or other co-morbid conditions that would limit compliance with the follow-up schedule of the study.;Angiographic Exclusion Criteria:
1. Subjects who are non-candidates for PCI.
2. Any of the target lesions meets any of the following criteria:
a. Aorto-ostial location (within 3 mm)
b. Lesion located in left main coronary artery
c. Lesion located within 2 mm of origin of the LAD or LCx
d. Lesion that involves a bifurcation with a side branch * 2mm in diameter and ostial lesion > 40% stenosed by visual estimation or side branch requiring intervention
e. Total occlusion (TIMI Flow 0), prior to wire crossing
f. Extreme tortuosity proximal to or within the lesion
g. Lesions having heavy calcification
h. Extreme angulation (* 90 %) proximal to or within the lesion
3. Evidence of previous revascularization:
a. Previous PCI with or without restenosis from previous intervention
b. Arterial or venous graft with or without lesion located within the graft or distal to a diseased arterial or saphenous vein graft
4. The target vessel contains visible thrombus.
5. Another (clinically significant or potentially significant) lesion left untreated within target vessels (including side branch) or another significant vessel.
6. Subject requiring or potentially requiring interventional procedures other than pre-dilatation and study device implantation and post dilatation.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	MeRes100 Sirolimus Eluting Bioresorbable Vascular Scaffold System
Registration:	No

Ethics review

Approved WMO Date:	08-12-2016
Application type:	First submission
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
ClinicalTrials.gov	NCT02663323
CCMO	NL56670.078.16