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A study to evaluate the safety and effectiveness of the Everoshine everolimus-eluting coronary stent

Submission date
23/11/2024

Recruitment status
No longer recruiting

Registration date
02/12/2024

Overall study status
Completed

Last Edited
19/03/2025

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Coronary artery disease is a disease in which the larger blood vessels of the heart (coronary arteries) become narrowed or blocked by fatty deposits, cholesterol and other substances. This results in chest pain or the death of heart cells. Percutaneous coronary intervention, a minimally invasive procedure with the implantation of a stent, is commonly used to treat blockages in the coronary arteries. Recently, a stent coated with polymers that release a drug has been used to treat patients with coronary artery disease. The drug prevents blockage of the arteries and once released the polymers degrade and are eliminated from the body. These stents are known as biodegradable polymer-coated drug-eluting stents. Everoshine is a biodegradable polymer-coated everolimus-eluting stent. It has already been approved by the regulatory authority of India for the treatment of symptomatic ischemic disease. This study aims to evaluate the safety and effectiveness of this stent in adult patients with coronary artery disease attributable to native coronary artery stenosis in routine clinical practice.

Who can participate?
Patients aged 18 years and over who required percutaneous coronary intervention

What does the study involve?
Patients will all receive the biodegradable polymer-coated everolimus-eluting stent. The study will track participants forward in time from the point of stent implantation, meaning the data will be collected as events unfold during the 1-year period.

What are the possible benefits and risks of participating?
Participation helps gather valuable data that can improve future care, stent technology, or treatment protocols for percutaneous coronary intervention. The outcomes from clinical investigations may lead to the development of safer, more effective coronary stents, advancing patient care globally. Trial results can help confirm the safety and efficacy of new or improved stent technologies, supporting regulatory approval and broader clinical adoption.

As with any procedure, the implantation of a stent carries the risk of bleeding, infection, blood vessel injury, or contrast-related kidney issues. Newer stents or procedural approaches could introduce additional risks.

Where is the study run from?
Sunshine Hospital Hyderabad (India)

When is the study starting and how long is it expected to run for?
September 2020 to February 2023

Who is funding the study?
Kamal Encon Industries Limited (India)

Who is the main contact?
Mr Abhishek Masalawala, a.masalawala@kecindustries.com

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinical evaluation of everoshine (everolimus-eluting coronary stent system)

Acronym
EveroStudy

Study objectives
This post-marketing surveillance study aims to evaluate the incidence of adverse events, including stent thrombosis, restenosis, myocardial infarction, and mortality in patients receiving the Everoshine drug-eluting stent.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 28/09/2020, Institutional Ethics Committee, Sunshine Hospitals (Sunshine Hospitals, Beside Paradise Hotel, PG Road, Secunderabad , Hyderabad, 500016, India; +91 (0)40-44550000; irb@sunshinehospitals.com), ref: SIECl2020l 410

Study design
Single-center non-randomized PMS study

Primary study design
Interventional

Study type(s)
Safety, Efficacy

Health condition(s) or problem(s) studied
Ischemic heart disease

Interventions
The study will track participants forward in time from the point of stent implantation, meaning the data will be collected as events unfold during the 1-year period. Both the participants and investigators will know the type of stent being implanted, which may affect patient behavior or follow-up care. However, there will be no blinding to the treatment. Patients will not be randomly assigned to different treatment groups (e.g., new stent vs. standard stent), which

means they will all receive the biodegradable polymer-coated everolimus-eluting stent. This design is typically used when randomization is not feasible or ethical, or when investigating a device with prior evidence.

Intervention Type
Device

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Everoshine drug eluting stent

Primary outcome(s)
A composite of major adverse events (MACE) like cardiac death, non-cardiac death, myocardial infarction (MI) and revascularization of the target vessel measured via clinical follow-up and pre-defined outcomes at 30 days

Key secondary outcome(s))
1. The rate of stent thrombosis measured via clinical follow-up and pre-defined outcomes at 30 days and 1 year
2. Cardiac death, non-cardiac death, MI, and target lesion revascularization (TLR) measured via telephonic follow-up and predefined outcomes at the 1-year follow-up

Completion date
21/02/2023

Eligibility

Key inclusion criteria
1. Patient with age at least 18 years.
2. The patient who agrees to participate in the study by signing the EC-approved informed consent form or alternatively, the patient's legally authorized representative (LAR) agrees to the patient's participation by signing the informed consent form.
3. Suitable for implantation of one or more Everolimus Eluting Coronary Stent System in one or more native artery target lesions.
4. Patient with indication, lesion length and target lesion(s) vessel diameter according to the Indications and 'Instructions for Use' given with every Everoshine Everolimus Eluting Coronary Stent System.
5. The patient who fully agrees and are able to cooperate with clinical procedures and required follow-up.
6. The patient must agree not to participate in any other clinical study for a period of 1 year following the index procedure.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
193

Key exclusion criteria
1. Patient with a known diagnosis of acute myocardial infarction (AMI) preceding the index procedure (CK-MB ≥2 times the upper limit of normal).
2. Patient with known left ventricular ejection fraction (LVEF) of <30%
3. Patient with a heart transplant or any other organ transplant or on a waiting list for any organ transplant
4. Female patients with known pregnancy or who are lactating.
5. Patients with known hypersensitivity or allergies to aspirin, heparin, clopidogrel, ticagrelor, ticlopidine, everolimus or similar drugs, or any other analogue or derivative, cobalt, chromium, nickel, molybdenum or contrast media
6. Patients in whom anti-platelet and/or anticoagulation therapy is contraindicated
7. Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon
8. Current medical condition with a life expectancy of less than 12 months
9. Patients who are receiving immunosuppressive therapy or have known serious immunosuppressive disease (e.g., HIV) or severe autoimmune disease that requires chronic immunosuppressive therapy (e.g., SLE etc)
10. Patients who are receiving or plan to receive chronic anticoagulation therapy (e.g., heparin or coumadin).
11. Subject has received brachytherapy in any epicardial vessel (including side branches).
12. The subject is participating in another device or drug study. Subject must have completed the follow-up phase of any previous study at least 30 days prior to enrolment in this trial.
13. Patients with medical conditions that preclude the follow-up as defined in the protocol or that otherwise limit participation in this registry
14. Patients with saphenous vein grafts of the target vessel
15. Drug-eluting stent treatment if done within 90 days prior to the index procedure
16. Subject has known renal insufficiency (e.g., serum creatinine level of >2.5 mg/dL or subject is under dialysis)
17. Platelet count <1,00,000 cells/mm3 or >7,00,000 cells/mm3, WBC of < 3,000 cells/mm3
18. Patient requirement to implant DES other than Everolimus Stent in any of the lesions of the target vessel

Date of first enrolment
08/10/2020

Date of final enrolment

28/08/2021

Locations

Countries of recruitment
India

Study participating centre
Sunshine Hospital
Secunderabad
India
500016

Sponsor information

Organisation
Kamal Encon Industries Limited

Funder(s)

Funder type
Industry

Funder Name
Kamal Encon Industries Limited

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/03/2025	19/03/2025	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes