

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 02/12/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 19/03/2025	Condition category Circulatory System	<input type="checkbox"/> 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

Study website

<https://www.kamalmedtech.com>

Contact information

Type(s)

Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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: SIECL2020I 410

Study design

Single-center non-randomized PMS study

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Safety, Efficacy

Participant information sheet

Not available in web format

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

Pharmaceutical study type(s)

Not Applicable

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Everoshine drug eluting stent

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

28/09/2020

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

100 Years

Sex

Both

Target number of participants

193

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

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Sponsor information

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Sponsor type

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Funder(s)

Funder type

Industry

Funder Name

Kamal Encon Industries Limited

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal.

Intention to publish date

05/12/2024

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