A Pro**s**pective, multicentre, registry to eval**u**ate the **C**linical out**c**ome of Encruso RAL-Everolimus **E**luting Coronary **S**tent **S**ystem in real world percutane**O**us coronary revascula**r**ization in Indian population - **SUCCESSOR**

Sponsor	Nano Therapeutics Pvt. Ltd. Plot no. D-54/2, Hojiwala Industrial Estate, Road No. 23, Near Gate No. 3 Sachin Palsana Highway, Sachin, Surat-394230, Gujarat, India
Main Study Study Chair	Dr. Upendra Kaul Chairman Batra Heart Centre and Dean Academics and Research Batra Hospital and Medical Research Centre, New Delhi-62
Main Study Study Co-Chair	Dr. Praveen Chandra Chairman- Interventional & Structural Heart Cardiology Medanta-The Medicity,Gurugram, Haryana
OCT sub study Study Chair	Dr. Viveka Kumar Principal Director & Chief of Cath Labs Max Super Specialty Hospital, New Delhi
CRO	Clicebo Solutions Private Limited N-28, Ground Floor, C.R.Park, New Delhi-110019, India
Study device	Encruso RAL -Everolimus Eluting Coronary Stent System
Phase	Registry
Protocol version and Date	1.0 dated 27 Nov 2021

STUDY SYNOPSIS

<table>
<tr><td>Title</td><td>A Pro<u>s</u>pective, multicentre, registry to eval<u>u</u>ate the <u>C</u>linical out<u>c</u>ome of Encruso RAL-Everolimus <u>E</u>luting Coronary <u>S</u>tent <u>S</u>ystem in real world percutane<u>O</u>us coronary revascula<u>R</u>ization in Indian population - SUCCESSOR</td></tr>
<tr><td>Phase</td><td>Registry/Observational</td></tr>
<tr><td>Study design</td><td>Prospective, multi-center, non-randomized, registry study.
Clinical follow up at 30days, 180days, year1 and year 2 post index procedure.</td></tr>
<tr><td>Planned Number of Patients</td><td>500 patients to receive treatment with the Encruso RAL-Everolimus Eluting Coronary Stent. No formal power calculations have been performed as this is an observational registry.</td></tr>
<tr><td>Planned Number of Sites</td><td>Up to 25 sites in India</td></tr>
<tr><td>Primary Objective</td><td>To evaluate the safety and efficacy of the Encruso RAL-Everolimus eluting coronary stent system implanted during routine clinical practice in India at 1 year follow up</td></tr>
<tr><td>Study device</td><td>Encruso RAL-Everolimus Eluting Coronary Stent System

The Encruso RAL-Everolimus Eluting Coronary Stent System Comprises of Following Components:
L605 Cobalt Chromium alloy stent
Biodegradable polymers
Drug – Everolimus (1.20µg/mm^2)
Stent strut thickness 60 µm ±10 µm
Available stent sizes<table><tr><td>Stent length</td><td>8,12,16,20,24,28,32,36,40,44,48 ,52</td></tr><tr><td>Stent diameter</td><td>2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00, 4.50</td></tr></table></td></tr>
<tr><td>Inclusion Criteria</td><td>Male or female patient who is 18 years and above
Patients undergoing percutaneous coronary intervention with Encruso RAL-Everolimus Eluting Coronary Stent System
Patient or legal guardian understands the study requirements and provides written informed consent
Patient who is on dual antiplatelet therapy for at least 6 months post procedure</td></tr>
<tr><td>Exclusion Criteria</td><td>Patient has known hypersensitivity or allergies to Aspirin, Heparin, Clopidogrel, Ticlopidine, Everolimus or similar drugs, or any other analogue or derivative, cobalt, chromium, or contrast media
Patient with life expectancy less than 2 years
Pregnant and lactating females or planning to become pregnant while in the study
Patient currently participating in another investigational drug or device clinical trial</td></tr>
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Primary Endpoints	• Target Lesion Failure (TLF) rate • A composite endpoint of Cardiac Death • Target Vessel related Myocardial Infarction(MI) and • Clinically driven Target Lesion Revascularization (TLR) at 1 year follow-up
Secondary Endpoints	Clinical endpoints measured at 2-year: • Target Vessel Failure (TVF) rate • ID-TVR • ID-TLR • TV-MI • Patient oriented composite endpoint (a composite endpoint of all cause death, all myocardial infarction, and all revascularization) • Major Adverse Cardiac Events (MACE) which is the composite endpoint of cardiac death, non-fatal myocardial infarction and non-fatal stroke • Nonfatal MI • Cardiac death(death from cardiac cause) • All cause death(including cardiac & non cardiac death) • Stent thrombosis (defined by Academic Research Consortium [ARC]criteria) Procedural endpoints: • Device success (residual coronary stenosis less than 50 %, normal coronary flow and absence of coronary dissection) • Device success and absence of PCI complication (periprocedural MI, coronary perforation, urgent CABG or death) or revascularization within 3 days
Sub study (optional)	50 patients from few selected sites and who satisfy all other SUCCESSOR study inclusion and exclusion criteria will be included in the OCT sub study. The primary objective of the study is to evaluate the malapposition, degree of strut coverage and vessel wall response after implantation of Encruso RAL-Everolimus Eluting Coronary Stent by Optical Coherence Tomography at 6 months angiographic follow up. The sub study is designed to run seamlessly with the main study but sites can opt out if they choose not to participate.