



SMT Announces Completion of Patient Enrolment for TUXEDO-2 Trial

Study synopsis:

- **Study Design and Objectives:** TUXEDO-2 compares Supraflex Cruz versus Xience stent in diabetic patients with multivessel coronary disease and evaluates the outcomes with PCI when compared with historical CABG data from the FREEDOM trial.
- **Impact and Future Prospects:** Preliminary results, to be presented at TCT 2025, are expected to provide insightful information on patient management through Supraflex Cruz and influence diabetic coronary treatment.

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SMT (Sahajanand Medical Technologies), a global leader in innovative medical devices, proudly announces the completion of patient enrolment for the Tuxedo 2 clinical trial in India. This landmark trial aims to evaluate the efficacy and safety of Supraflex Cruz Drug-Eluting Stent (DES) in diabetic patients with multivessel coronary artery disease (CAD).

The Tuxedo 2 trial is designed to challenge existing paradigms in the treatment of multivessel CAD among diabetic patients, building on the insights from previous studies like the FREEDOM trial. The trial seeks to address the unique challenges faced by diabetic patients who are at a higher risk of adverse outcomes following percutaneous coronary interventions (PCI).

TUXEDO-2 is a prospective, multicentre, open-label, randomized trial initiated on February 25, 2020. The trial completed enrolment on August 6, 2024, with 1,800 patients across 63 centres in India.

Key highlights:

Focus: The study assesses primary endpoints such as target lesion failure (TLF) at 12 months, major adverse cardiac events (MACE), and stent thrombosis, along with secondary and tertiary objectives related to CABG and antiplatelet therapies (Ticagrelor vs. Prasugrel).

Innovation: Utilizing SMT's latest generation DES technology, the study aims to improve vascular healing and reduce restenosis rates.

Lead investigator on the study and Padma Shri Dr Upendra Kaul stated, "This is the only prospective randomized study where a biodegradable polymer DES has been compared head on with the international market leader durable polymer DES Xience in diabetics with multi-vessel disease. In addition, Prasugrel will be compared with ticagrelor for death, MI, stroke, or BARC major bleeding in a very high-risk population."



Dr Sripal Bangalore, Tenured Prof of Medicine at New York university School of Medicine added, "This is the only study in diabetics with multi-vessel disease after FREEDOM trial where a reappraisal of the superiority of CABG with contemporary PCI is being done on all cause death, nonfatal MI, or stroke (MACE)."

The Tuxedo 2 trial is poised to provide valuable data that could potentially redefine treatment strategies for diabetic patients with complex coronary artery disease. By leveraging SMT's innovative stent technology, the trial aims to deliver improved clinical outcomes and enhance the quality of life for patients.

This trial is a testament to SMT's dedication to developing cutting-edge solutions that address the unmet needs of this high-risk patient population. SMT extends its gratitude to the patients, investigators, and clinical partners who have contributed to the successful enrolment of this trial.

About SMT

SMT is a global medical device company committed to make advanced medical technologies accessible to everyone around the world. With presence in 80 countries, SMT has achieved recognitions from the Ministry of Health Sciences & Technologies for its tremendous contributions in the field of coronary healthcare. SMT also pioneered the introduction of biodegradable polymers in the cardiovascular segment. SMT will continue the journey to heal hearts around the world by creating healthcare future promising for everyone.

About Supraflex Cruz

The Cruz design provides physicians access to difficult and tortuous lesions which are particularly challenging in their practice. The stent retains all the benefits of Supraflex stents or the previous "Supra" family of stents, viz, thin struts, a blend of proprietary biodegradable polymers to release the drug, high radial strength, and low crossing profile. Supraflex Cruz has a large and extensive size matrix, covering diameters from 2.0 to 4.5 and lengths from 8 mm to 48 mm. This size matrix ensures no compromises in the coronaries for either physician or patient.

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