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ASIA EDITION

World's first clinical trial with Sirolimus Coated Balloon for the treatment of SFA begins

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The FUTURE SFA trial is designed to determine the effectiveness of MagicTouch PTA sirolimus drug-coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal arterial disease.



Singapore's Concept Medical Inc., focused on vascular intervention drug delivery devices, on 15 Sep 2020 has announced the enrolment of the first patient in the **FUTURE SFA** (Randomized Controlled Trial of **F**irst Sirolim**U**s Coa**T**ed Balloon Vers**U**s Standa**R**d Balloon Angioplasty in The Tr**E**atment of **S**uperficial **F**emoral **A**rtery and Popliteal Artery Disease).

FUTURE SFA is a randomized, double blind, placebo-controlled, multi-center trial to determine the effectiveness of MagicTouch PTA sirolimus drug coated balloon versus standard percutaneous transluminal angioplasty for the treatment of superficial femoral and popliteal arterial disease.

In its most advanced stage, peripheral arterial disease (PAD) patients present as critical limb ischemia (CLI) and many end up with leg amputations.

Current standard of care for severe PAD is revascularization, the majority of which involves the use of balloon angmedioplasty to unblock the vessel and restore blood flow to the leg. However, these vessels frequently become blocked again, resulting in repeated procedures which is potentially dangerous and may result in loss of limb or even life.

Local drug delivery using drug coated balloons (DCBs) during angioplasty can successfully deliver anti-proliferative drugs to the lesions in the artery, with the aim of keeping the vessel open for longer. Sirolimus coated balloons are considered to be the next new generation of DCBs and the novel MagicTouch PTA sirolimus coated balloon (SCB), has emerged as one of the most promising transcatheter technologies in preventing restenosis for diseased arteries.

The principal investigator of FUTURE-SFA is Associate Professor Edward Choke from the Department of General Surgery (Vascular Surgery) at the Sengkang General Hospital, Singapore.

Associate Professor Edward Choke said, "I am inspired by the bold, imaginative and futuristic concepts presented by the Nanolute technology of the MagicTouch PTA sirolimus coated balloon. In contrast to other contemporary technologies, MagicTouch PTA offers a solution that optimizes both the deliverability and the absorption of sirolimus into the vessel wall."

He added, "Initial experience with the XTOSI first in man study suggested that MagicTouch PTA can provide an effective way of revascularization for PAD patients, by keeping the vessels open longer and reducing the need of repeated angioplasty procedures. I look forward to the FUTURE-SFA randomized controlled trial, which will test whether the Magic Touch PTA sirolimus coated balloon can improve the patencies of femoral and popliteal arteries in PAD patients. We hope to establish whether SCB will emerge as the new standard of care which will impact the way we treat PAD."

The trial will enrol 153 patients with Rutherford class 3 to 6 PAD. These subjects will be randomized in 2:1 fashion to receive either Magic Touch PTA or standard balloon angioplasty. Primary outcome will be primary patency at 6 months, defined as duplex peak systolic velocity ratio (PSVR) of 2.4 or less.

The trial is designed to follow a rigorous blinding protocol in order to minimise bias. Patients, care providers, investigators and outcome assessors, including vascular technologists performing the duplex ultrasound, will be blinded to the treatment allocations. The patients will be followed up for two years.