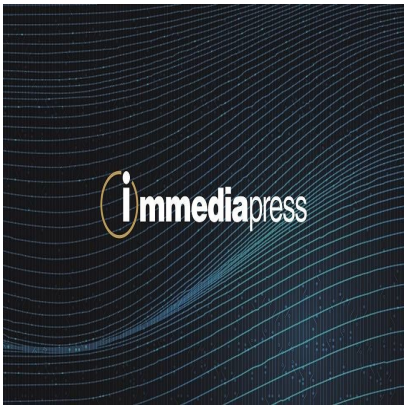

SirPAD: Primary Results confirm the safety and efficacy of Sirolimus Coated Balloon in PAD

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

TAMPA, Fla., March 31, 2026 /PRNewswire/ â?? Concept Medical Inc. (CMI), a global leader in innovative drug-delivery technology across vascular interventions, proudly announces the presentation of the worldâ??s largest randomised controlled trial of a Sirolimus-coated balloon for Peripheral Artery Disease (SirPAD) at the ACC 2026 Scientific Sessions.

The primary results of the SirPAD trial were presented as a Late Breaking Clinical Presentation by Prof. Dr. Stefano Barco from the University Hospital Zurich on behalf of SirPAD Steering Committee members and investigators. The primary results of the SirPAD trial have been simultaneously published in the New England Journal of Medicine.

The academic, all-comers SirPAD trial enrolled 1,252 patients with femoropopliteal or below-the-knee PAD who were randomized to receive either the sirolimus-coated balloon MagicTouch PTA or any uncoated balloon angioplasty. The primary outcome of major adverse limb events (MALE), encompassing major unplanned amputations affecting the target limb or target-lesion revascularization for critical ischemia, occurred in 8.8% of patients enrolled in the sirolimus-coated balloon group vs. 15% in the uncoated balloon group at one year, corresponding to a median unbiased estimate of the risk difference of -4.9%. This difference was both noninferior and superior in favour of MagicTouch PTA (Concept Medical Inc.) vs. uncoated balloon. Furthermore, the authors showed a statistically significant reduction in the composite key secondary endpoint of any unplanned target-limb amputation or any target limb revascularization.

â??We are excited about the primary outcome results of SirPAD. It is one of the very few trials in this field that successfully included an all-comers population, meaning consecutive patients without eligibility restrictions related to target-lesion characteristics or PAD stage. This led to nearly 50% of enrolled patients having acute or chronic limb-threatening ischemia, thereby providing enough events and statistical power to demonstrate superiority for hard clinical outcomes at one year,â?• said Principal Investigators Prof. Dr. med. Nils Kucher and Prof. Dr. med. Stefano Barco, co-chairs of this

groundbreaking trial after the presentation.

SirPAD is a gamechanger trial with the data marking a turning point in the vascular intervention and MagicTouch PTA sirolimus-coated balloon emerging as a future treatment alternative. MagicTouch sirolimus-coated balloon is the most clinically studied drug coated balloon and is creating the highest clinical evidence in both coronary and peripheral domains. The recently conducted SIRONA RCT in the femoropopliteal PAD against Paclitaxel DCBs also confirmed the non-inferiority of MagicTouch PTA. With the primary analysis published of the SirPAD trial, there is proof of efficacy that Sirolimus drug coated balloon improves clinical outcomes in an-all comers population with potential impact on future guidelines, thus expanding the available treatment options with physicians.

â??SirPAD is an important milestone for the PAD community and for the continued evolution of sirolimus-coated balloon therapy. Seeing MagicTouch PTA evaluated in a large, investigator-led randomized trial and supported by peer-reviewed publication reinforces our belief that meaningful innovation must be validated through rigorous science. We are grateful to the investigators, study teams, and patients who made this landmark study possible,â?• said Dr. Manish Doshi, Founder and Managing Director of Concept Medical and inventor of MagicTouch.

Source: Data from SirPAD, presented as a Late-Breaking Clinical Trial at the 75th American College of Cardiology (ACC) Conference by Prof. Dr. Stefano Barco on March 30, 2026, in New Orleans, LA, USA, and simultaneously published in the New England Journal of Medicine.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. For restricted use only in countries where product registered with applicable health authorities. MagicTouch PTA is an investigational device approved by USFDA for use in clinical trials only.

Logo: https://mma.prnewswire.com/media/1926812/5367429/Concept_Medical_Logo.jpg

View original content:https://www.prnewswire.co.uk/news-releases/sirpad-primary-results-confirm-the-safety-and-efficacy-of-sirolimus-coated-balloon-in-pad-302729708.html

Categoria

1. Comunicati

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1. ImmediaPress

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