

Medis Medical Imaging partners with CORRIB Core Lab and SINOMED, to study impact of Quantitative Flow Ratio (QFR®) on appropriateness of revascularization in the PIONEER-IV randomized clinical trial

This PIONEER IV study is a randomized, multicenter trial comparing clinical outcomes between angiography-derived physiology guidance by QFR® of Medis Medical Imaging and local routine diagnostic procedure and usual care in an all-comers patient population undergoing PCI with an unrestricted use of SINOMED's new drug-eluting stent, the Healing-Targeted Supreme Stent (HT Supreme).

The PIONEER-IV study will involve careful physiological identification of heart blood vessels that need to be treated or deferred. A narrowing located in a coronary vessel is deemed flow limiting if QFR <0.80 . After stenting, the QFR measurement is repeated in the stented vessel(s) to verify the success of the intervention. In case distal QFR is <0.91 or delta QFR (across the stent is >0.05), post-dilatation of stented segment or additional stenting is recommended.

The PIONEER-IV trial will take place in 30 hospital centres across Europe and involve 2,540 coronary artery disease patients.

The trial is sponsored by NUI Galway and it will be centrally coordinated by the University's CORRIB Research Centre for Advanced Imaging and Core Laboratory.

This Pioneer IV trial will be executed with the QFR®-software of Medis Medical Imaging as the image-based solution for the physiologic assessment of the severity of coronary lesions.

The trial is co-chaired by NUI Galway's CORRIB Core Lab, led by Professor Patrick W Serruys, Established Professor of Interventional Medicine and Innovation, and Professor William Wijns, Science Foundation Ireland Professor of Interventional Cardiology, both of whom are internationally renowned experts in interventional cardiology and cardiovascular disease.

Patrick Serruys, Chief Investigator on behalf of NUI Galway said:

“This trial is of paramount importance and is a critical attempt at replacing pressure-wire guidance by a physiological guidance derived from conventional coronary angiography using the on-line QFR® software of Medis Medical Imaging . The cost-effectiveness of this approach is obvious and may signify a turning point in the physiological guidance of PCI. Furthermore, the trial is an all-comers trial, applying novel P2Y12 monotherapy and using a stent specially designed for fast and healthy endothelial coverage of the struts: the Healing Targeted Supreme DES”.

Professor Onuma, medical director of the CORRIB corelab, said:

The PIONEER IV trial is unique in randomizing all-comer patients. This trial may pave a way to facilitate the adoption of physiology-guided stenting by performing on-line QFR® in all patients treated in a cathlab. The standard use of HT Supreme DES in the PIONEER IV trial will promote the short-DAPT strategy rationalized by its excellent early tissue coverage as demonstrated on optical coherence tomography in the PIONEER-II study, and eliminate any potential bias caused by the selection of different DES type.

Professor Escaned, co-PI of the study, said: PIONEER-IV is the first trial exploring the use of image-based physiology for both planning and optimization of percutaneous coronary interventions. As this strategy will be tested in an unselected, all-comers patient population, the results of PIONEER IV will complement those of ongoing trials like FAVOR III comparing QFR® and FFR in more selected patients.

Professor Johan HC Reiber, Chief Scientific Officer at Medis Medical Imaging , said: We are pleased that CORRIB Core Lab has chosen QFR® as the image-based solution for the physiologic assessment of the severity of the coronary lesions in this Pioneer IV Trial. The QFR® has proven its robustness and quality in over more than 15.000 patients collected in European and Asian countries and the results have been published in more than 105 peer-reviewed scientific publications.

About Medis Medical Imaging

Medis Medical Imaging develops, markets and supports high quality and powerful software with innovative post-processing solutions for cardiovascular imaging. Medis has been developing software solutions to support the healthcare professionals in their CT, MR, X-Ray and Ultrasound procedures for over thirty years. Medis' multi-modality software is best in class and vendor independent, it can be used in both scientific research and in clinical routines. Powered by artificial intelligence, Medis software incorporates innovative algorithms speeding up workflow, maximizing reproducibility and providing diagnostic confidence. At Medis we are constantly improving our products, supporting healthcare professionals with determining the best diagnosis and the subsequent treatment strategies for all patients.

Medis, imaging solutions in a heartbeat.

To learn more about Medis Medical Imaging , visit www.medisimaging.com

About CORRIB Core Lab

The CORRIB Core Lab is a centre of excellence for innovation, research, collaboration and education at the National University of Ireland, Galway. The CORRIB Research Center for Advanced Imaging and Core Laboratory provides cutting-edge imaging methods and decades of cardiovascular imaging expertise to assess the imaging component of these trials and registries to ensure they are reproducible and yield the best outcomes.

More information on the CORRIB Core Lab is available here <http://www.nuigalway.ie/corrib-corelab/>

About SINOMED

SINOMED is a global medical device company engaged in research, development, production, and commercial distribution of interventional devices. We are focused on developing breakthrough technologies to target unmet clinical needs in the interventional treatment of coronary, neurovascular and structural heart disease. Our mission is to expose more patients to the benefits of our medical innovations, increasing patient longevity and quality of life. For more information visit www.sinomed.com.