

MedStar Heart Institute and Infraredx, Inc Initiate the Lipid Rich Plaque (LRP) Study to Evaluate Prediction of Heart Attacks

Business Wire

MedStar Heart Institute of Washington, D.C. and Infraredx, Inc., a medical device company committed to advancing the diagnosis and management of coronary artery disease, today announced the initiation of the Lipid-Rich Plaque (LRP) Study, a prospective, multi-center study designed to evaluate the ability of intravascular imaging to identify patients with LRPs who are at a higher risk for heart attacks and other serious coronary events. LRPs are a type of fatty coronary artery plaque implicated in most heart attacks, and will be identified using the Infraredx TVC Imaging System™, a first-in-class catheter-based intravascular imaging technology. The study, which will be sponsored by Infraredx, seeks to enroll 9,000 patients, and will examine the correlation between the presence of LRPs and the occurrence of a cardiac event during the 24 months after imaging.

MedStar Heart Institute is one of 100 clinical sites across the country to participate in the trial. MedStar Heart Institute, headquartered at MedStar Washington Hospital Center, is a national leader in the research, diagnosis and treatment of cardiovascular disease, and is consistently recognized by U.S. News & World Report and The Society of Thoracic Surgeons.

Coronary artery plaques are caused by the build-up of cholesterol and other materials inside the walls of the coronary arteries. Over time, the accumulation of plaque can gradually reduce blood supply to the heart, leading to chest pain during exertion. In addition, the plaques may also rupture which can lead to a blood clot that causes a heart attack or sudden death.

The TVC Imaging System integrates near-infrared spectroscopy (NIRS) lipid core plaque detection technology, and enhanced intravascular ultrasound (IVUS) imaging to visualize the presence of plaques, quantify the degree of vessel stenosis (narrowing) and identify plaques suspected to be prone to rupturing and causing dangerous blockages. Current methods of diagnosing coronary artery disease are limited in their ability to detect such plaques.

“This innovative and uniquely designed study will finally answer the decades-old question of whether or not we can accurately identify a vulnerable plaque” said Ron Waksman, MD, director, Cardiovascular Research and Advanced Education with MedStar Heart Institute, and the International Principal Investigator of the LRP Study. “The LRP Study will utilize the TVC System to identify lipid rich plaques in patients undergoing stenting. We will then follow the patients for two years to determine if these suspected vulnerable plaques cause coronary events.”
“Successful prediction in the study will permit us to identify patients and lesions at increased risk. We can then utilize treatment modalities, drug or device, or a

combination, to help mitigate this risk,” said Dr. Waksman. “We are excited to start and conduct this monumental and innovative study.” The study will be conducted in approximately 100 hospitals located throughout the world. Dr. Carlo Di Mario of London, England will serve as Principal investigator for Europe. Dr. Takeshi Akasaka of Wakayama, Japan will serve as Principal Investigator for Japan, a country with advanced coronary imaging experience. Dr. Yasunori Ueda of Osaka, Japan will serve as Co-Principal Investigator for Japan.

A recent study 1 published in the Journal of the American College of Cardiology Cardiovascular Interventions, demonstrated that NIRS imaging detected a distinct signature of a cholesterol plaque at the sites causing major heart attacks. A second study 2 found that increased cholesterol (detected by NIRS imaging) in a non-culprit artery indicated the patient had a 4-fold multivariate increase in risk of a coronary event over the subsequent year.

“We are pleased that our TVC Imaging System will now be tested for its ability to find the vulnerable plaques that cause coronary events, the leading cause of death in the developed world. Once at-risk patients are identified, it is very likely that current treatments could be utilized to prevent these harmful events,” said James Muller, MD, co-founder and chief medical officer of Infraredx.

The LRP study will start enrollment in December 2013 and conclude follow-up for the last patient in December 2017. The study will initially focus on validating the ability of NIRS-IVUS imaging to predict coronary events. If and when that goal is achieved, the study will transition to a blinded, randomized study of TVC-guided preventive treatment.

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