

CRF and UCR announce initiation of PROSPECT II clinical trial

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The Cardiovascular Research Foundation (CRF) of New York, NY and the Uppsala Clinical Research Center (UCR) of Uppsala, Sweden announced today the initiation of the PROSPECT (Providing Regional Observations to Study Predictors of Events in the Coronary Tree) II trial and the PROSPECT ABSORB sub study. PROSPECT II is an investigator initiated multicenter, prospective registry study which will assess the ability of intracoronary near infrared spectroscopy (NIRS) to identify non-flow obstructing vulnerable plaques which subsequently lead to coronary events. PROSPECT ABSORB is an investigator initiated multicenter, randomized trial, which for the first time will evaluate the ability of a bioresorbable scaffold to safely increase luminal dimensions of vulnerable plaque.

The PROSPECT II study will enroll 900 patients with [acute coronary syndrome](#) (ACS) and will be led by Gregg W. Stone MD, Professor of Medicine at Columbia University Medical Center in New York, and David Erlinge, MD, PhD, director of the Department of Cardiology, Lund University, Skane University Hospital in Lund, Sweden. Patient enrolment will begin in the first part of 2014 and be completed in approximately one year. The study will be conducted in approximately 16 sites in Scandinavia.

Each patient will be examined with intravascular ultrasound (IVUS) and NIRS in all three coronary arteries. In the PROSPECT ABSORB sub study, 300 patients with a plaque at high risk of causing future coronary events, as shown in the original PROSPECT study (plaque burden

≥70%), will be randomized to treatment with Absorb™ Bioresorbable Vascular Scaffold (BVS; Abbott) plus guideline directed medical therapy (GDMT) or GDMT alone, with each patient undergoing angiography and IVUS/NIRS after two years. All 900 patients will be measured at baseline and then followed in the registry for at least three years to detect the occurrence of [coronary events](#). The integrated PROSPECT II and PROSPECT ABSORB study program is being funded by grants from InfraReDx, The Medicines Company, and Abbott. Uppsala Clinical Research Center (UCR) will have the operational responsibility and be the sponsor of the study. The study will be conducted in academic partnership with the CRF Clinical Trials Center (CTC).

Data from the original PROSPECT trial demonstrated for the first time prospectively that vulnerable plaques that are most likely to cause sudden unexpected adverse cardiac events can be identified through imaging techniques, months to years before the adverse events occur. These study findings were published in the January 20, 2011 issue of the *New England Journal of Medicine*.

"Using the NIRS imaging technology to detect lipid rich plaque (LRP) has been an eye-opener for us. We can see in vivo that close to all patients with a ST-elevation myocardial infarction (STEMI) exhibit a LRP at the culprit site. In PROSPECT II we will determine the importance of LRP prospectively so that in the future, we can hopefully identify and treat the vulnerable plaque before the infarction happens," said David Erlinge, MD, PhD, Professor and Director of the Department of Cardiology, Lund University, Skane University Hospital in Lund, Sweden.

"Findings from the original PROSPECT study have helped physicians identify those lesions that are at especially high risk of causing future adverse cardiovascular events, using a combination of imaging

modalities based on IVUS," said Gregg W. Stone, MD. Dr. Stone is Professor of Medicine at Columbia University College of Physicians and Surgeons, Director of Cardiovascular Research and Education at the Center for Interventional Vascular Therapy at NewYork-Presbyterian Hospital/Columbia University Medical Center and Co-Director of the Medical Research and Education Division at CRF.

"NIRS has been extremely well validated for detecting lipid, which is at the core of most vulnerable plaques. PROSPECT II will determine the ability of NIRS to identify these high risk lesions in an adequately powered prospective study. And PROSPECT ABSORB will, for the first time, test the feasibility of an interventional approach in preventing future major adverse cardiovascular events arising from plaques which appear angiographically innocuous (and are thus not currently stented), but are in fact the source of future acute coronary syndromes. This is truly a groundbreaking investigation," said Dr. Stone.

Provided by Cardiovascular Research Foundation

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