

Enrollment completed for RE-DUAL PCI study of 2,700 atrial fibrillation patients

November 14 2016

The Baim Institute has announced that patient enrollment into the international Phase IIIb RE-DUAL PCI study is complete. The study evaluates the safety and efficacy of dabigatran etexilate in atrial fibrillation (AF) patients undergoing a percutaneous coronary intervention (PCI) with stent placement. This is the first time that two dosages of a non-vitamin K antagonist oral anticoagulant (NOAC) already approved for stroke prevention in AF are evaluated in a dual versus triple antithrombotic regimen after PCI.

"Up to 30% of AF patients may have <u>coronary artery disease</u> and require PCI with stenting, yet to date only limited data exists on the use of the NOACs during this procedure," said Dr. Christopher Cannon, RE-DUAL PCI Lead Investigator and Executive Director, Cardiometabolic Trials, Baim Institute for Clinical Research, who is a cardiologist at Brigham and Women's Hospital in Boston and a Professor of Medicine, Harvard Medical School. "The RE-DUAL PCI study will provide new insights into antithrombotic treatment approaches in AF patients requiring PCI.

"We expect the results to be highly clinically relevant for practicing physicians who treat patients such as these in routine care, as the study uses the two dabigatran doses already internationally approved for stroke risk reduction in AF," said Dr. Cannon.

The results of the RE-DUAL PCI study are expected during the second half of 2017. The study is sponsored by Boehringer-Ingelheim.



More information: 1. Clinicaltrials.gov. Evaluation of Dual Therapy With Dabigatran vs. Triple Therapy With Warfarin in Patients With AF That Undergo a PCI With Stenting (REDUAL-PCI). <u>https://clinicaltrials.gov/ct2/show/NCT02164864</u> Last accessed November 2016.

2. Cannon C.P. et al. Design and Rationale of the RE-DUAL PCI Trial: A Prospective, Randomized, Phase 3b Study Comparing the Safety and Efficacy of Dual Antithrombotic Therapy With Dabigatran Etexilate Versus Warfarin Triple Therapy in Patients With Nonvalvular Atrial Fibrillation Who Have Undergone Percutaneous Coronary Intervention With Stenting. Clin Cardiol. 2016;39(10):555-564. Available at http://onlinelibrary.wiley.com/doi/10.1002/clc.22572/full

Provided by Baim Institute for Clinical Research

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