CHI St. Luke's Health

Baylor St. Luke's Medical Center

in partnership with

Texas Heart® Institute

Cardiology Research Newsletter

Office of Clinical Research

Winter 2015 • Issue Two

Enrolling Cardiology Research Trials at Baylor St. Luke's Medical Center

Abdominal Aortic Aneurysms

LIFE*
Trivascular, Inc. • *Zvonimir Krajcer, MD*

LIFE Study: Least Invasive Fast-Track EVAR with the Ovation Prime™ Abdominal Stent Graft System. The primary objectives of the LIFE Study are to demonstrate the clinical and cost benefits associated with using the Ovation Prime Abdominal Stent Graft System under the least invasive conditions defined in the Fast-Track EVAR protocol. The key elements of the Fast-Track EVAR protocol include:

- Appropriate patient selection (i.e. candidate for Ovation Prime device, Inclusion/Exclusion criteria)
- Bilateral percutaneous access
- No general anesthesia (e.g. local or consciencesedation)
- No ICU admission post procedure
- Next day discharge (one midnight stay)

NELLIX
Endologix, INC • *Zvonimir Krajcer, MD*

Prospective, multicenter, single arm study with consecutive, eligible subject enrollment at each site. All subjects will undergo the Endovascular Aneurysm repair procedure with the Nellix System.

Electrophysiology

MICRA
Medtronic • *John Seger, MD*

The purpose of this clinical study is to evaluate the safety and efficacy of the Micra Transcatheter Pacing System and to assess long-term device performance. Subjects, who have a Class I or II indication for implantation of a single chamber ventricular pacemaker according to ACC/AHA/HRS 2008 guidelines and any national guidelines may be eligibile.

reMARQable
Biosense Webster • *Abdi Rasekh, MD*

The Main Study will consist of a prospective, multi-center, randomized (1:1 concurrent nMARQ™ Catheter System [nMARQ] vs THERMOCOOL® Navigational Family of catheters [TC]), controlled, twoarm, single-blind design. Embedded within the Main Study will be a Subpopulation Neurological Assessment (SNA) with a prospective, controlled design, with consecutive enrollment.

VICTORY AF
Medtronic • *Abdi Rasekh, MD*

The purpose of this clinical study is to evaluate the risk of procedure and/or device related strokes in subjects with persistent or long-standing persistent atrial fibrillation (AF) undergoing ablation with the Phased RF System.

ICY AVNRT
Medtronic • *John Seger, MD*

ICY-AVNRT (Intracardiac CrYoablation for AtrioVentricular Nodal Reentrant Tachycardia), a prospective multi-center, nonrandomized, single arm, controlled, unblinded, investigational clinical study. The purpose of this clinical study is to demonstrate the safety and effectiveness of the Freezor® Xtra Cardiac CryoAblation Catheter for the cryoablation of the conducting tissues of the heart in the treatment of patients with atrioventricular nodal reentrant tachycardia (AVNRT) using an endocardial approach.

AdaptResponse
Medtronic • *John Seger, MD*

The purpose of this clinical study is to test the hypothesis that market released CRT devices which contain the AdaptivCRT® (aCRT) algorithm have a superior outcome compared to standard CRT devices in CRT indicated patients with normal AV conduction and left bundle branch block (LBBB).

CV Anesthesia

AKI THRASOS*
Thrasos • *David Collard, MD*

A Phase II Multi-Center, Parallel-Group, Randomized, Double Blind, Proof-of-Concept, Adaptive Study Investigating the Safety and Efficacy of THR-184 Administered via Intravenous Infusion in Patients at Increased Risk of Developing Cardiac Surgery Associated-Acute Kidney Injury (CSA-AKI). The primary objectives of this study are to evaluate the safety, tolerability and efficacy of THR-184, when administered intravenously (IV) to patients at increased risk of developing CSA-AKI.

Coronary

Platinum DIVERSITY*
Boston Scientific • *Ali Mortazavi, MD*

To compile acute procedural performance and clinical outcomes data for the Promus PREMIER everolimus-eluting coronary stent system in understudied/underserved patient populations including women and minorities.

Lipid Rich Plaque (LRP)
Infraredx • *Brian Walton, MD*

The Lipid-rich Plaque Study will determine the relationship in patients undergoing IVUS-NIRS (near-infrared spectroscopy) imaging between lipid-rich plaque detected by intracoronary NIRS at non-stenotic sites and subsequent coronary events from new culprit lesions at both the patient level (vulnerable patients) and the segment level (vulnerable plaques).

AVERT*
Osprey Medical • *Guilherme Silva, MD*

The purpose of this trial is to assess the AVERT System device for CM volume reduction and incidence of CIN. Subjects will be considered for enrollment in this study if they are considered at risk for the development of CIN and determined to need a coronary procedure requiring iodinated CM.

ABSORB IV*
Abbott Vascular • *Emerson Perin, MD*

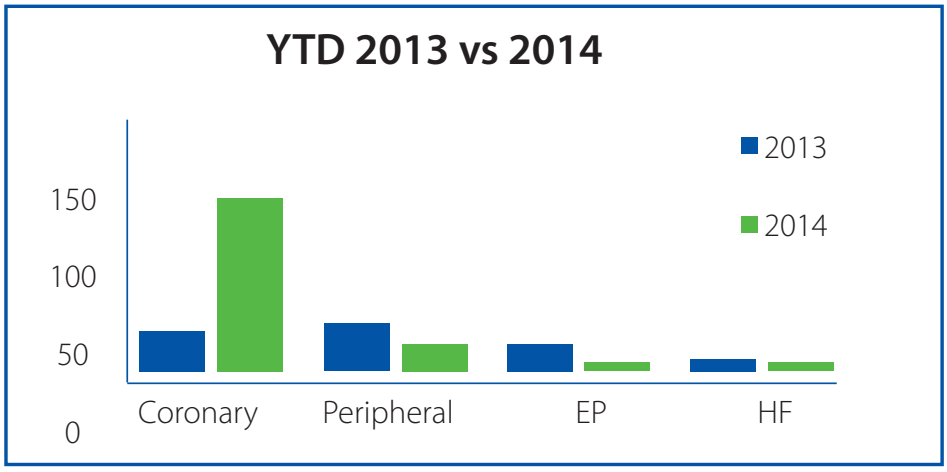
Primary Objective: To evaluate the safety and effectiveness of the ABSORB BVS System against the XIENCE V EECSS in the treatment of subjects with ischemic heart disease caused by up to two de novo native coronary artery lesions in separate epicardial vessels. A prospective, randomized (2:1 ABSORB BVS to XIENCE V), single-blind, multi-center trial, registering approximately 5450 subjects at approximately a total of 160 sites within the United States (US) and Outside the US, to be conducted in two sequential cohorts.

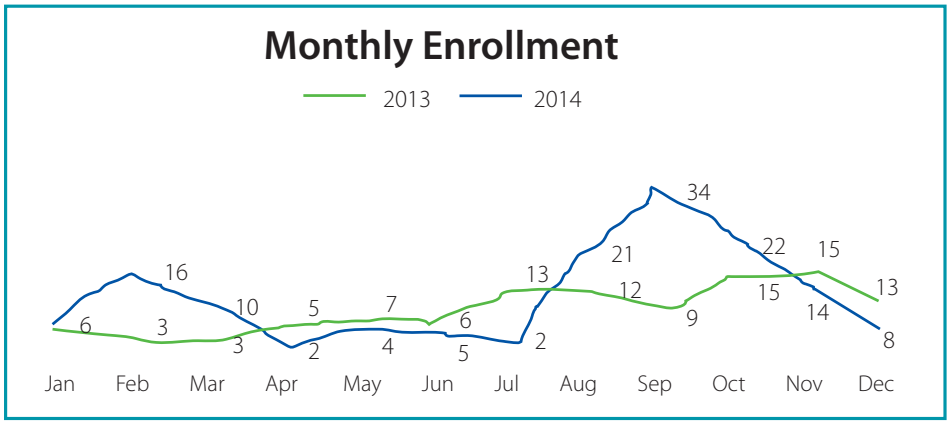
Heart Failure

INOVATE - HF
Bio-Control Medical, Ltd. • *Reynolds Delgado, MD*

INcrease Of VAgal TonE in chronic Heart Failure (INOVATE-HF) - A Randomized Study to establish the Safety and Efficacy of CardioFit for the Treatment of Subjects with Heart Failure and Left Ventricular Dysfunction. Patients with LV systolic dysfunction (EF < 40%) and heart failure in NYHA functional class III, who have failed to achieve symptom relief despite standard evidence-based management per applicable guidelines may be eligible.

Patient Accural Summary	
Service	**# Patients YTD**
Coronary	118
Peripheral	17
Electrophysiology	7
Heart Failure	6
TOTAL	**148**





*Opens Quarter 1 2015.

New at Baylor St. Luke's: Remarqable Study

nMARQ™ Pulmonary Vein Isolation System for the Treatment of Paroxysmal Atrial Fibrillation" Sponsored by Biosense Webster; Abdi Rasekh, MD, Principal Investigator

Main inclusion criteria:

1. Patients with symptomatic paroxysmal AF who have had at least one AF episode documented within one year prior to enrollment. Documentation may include ECG, transtelephonic monitor (TTM), Holter monitor (HM), or telemetry strip.
2. Patients who have failed at least one antiarrhythmic drug (AAD; class I or III, or AV nodal blocking agents such as beta blockers and calcium channel blockers) as evidenced by recurrent symptomatic AF, or intolerance to the AAD.

For full inclusion and exclusion, contact the Research Coordinator at 832.355.3710 or ocr@stlukeshealth.org.