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CHI St. Luke's Health

Baylor St. Luke's Medical Center

Texas Heart® Institute

Baylor College of Medicine

Issue #5

Baylor St. Luke's Medical Center CV Research Newsletter

New Enrolling Trials

A complete list of trials at BSLMC can be found on the website:
http://research.chistlukeshealth.org/OurServices/Research/SearchForm.cfm

AMAZE Trial (H-37863)

Left Atrial Appendage Ligation with the LARIAT+® Suture Delivery System as Adjunctive Therapy to Pulmonary Vein Isolation (PVI) for Persistent or Longstanding Persistent Atrial Fibrillation

Principal Investigator: Abdi Rasekh, MD **Sponsor:** SentreHeart, Inc.

This is a (2:1) randomized controlled trial to evaluate the safety and effectiveness of the LARIAT System to percutaneously isolate and ligate the left atrial appendage from the left atrium as an adjunct to planned pulmonary vein isolation (PVI) catheter ablation in the treatment of subjects with symptomatic persistent or longstanding persistent atrial fibrillation.

Main Inclusion Criteria:

1. Documented diagnosis of symptomatic persistent or longstanding persistent non-valvular atrial fibrillation
2. Failed at least one Class I or III antiarrhythmic drug (AAD)

Main Exclusion Criteria:

1. Prior epicardial or endocardial atrial fibrillation ablation procedure
2. LA diameter > 6 cm as measured by computerized tomography

AMAZE contact:

Stephen Harold
harold@bcm.edu
832-355-3710

GORE TAG (H-37148)

Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis in the Treatment of DeBakey Type I/II Aortic Dissection

Principal Investigator: Joseph Coselli, MD **Sponsor:** W.L. Gore & Associates, Inc.

This study is a prospective, multicenter, non-randomized single-arm study to assess the feasibility of the treatment of DeBakey Type I/II aortic dissections with the GORE® TAG® Thoracic Branch Endoprosthesis system.

Main Inclusion Criteria:

1. DeBakey Type I/II aortic dissection compatible with the treatment requirements of TBE, including:
    - Primary entry tear must be in the ascending aorta and ≥2cm distal to the most distal coronary artery ostia
    - Ascending aorta true lumen diameter compatible with TBE Aortic Extender Components (24mm – 48mm)
2. Able to undergo CT scan per protocol requirements to perform required case planning prior to endovascular procedure

Main Exclusion Criteria:

1. Planned aortic valve repair or replacement or coronary artery intervention within 30 days
2. Primary entry tear location in the aortic arch or descending thoracic aorta with retrograde flow into the ascending aorta
3. Aortic insufficiency grade 3+ or 4+

GORE TAG contact:
Laurie Fondren
Fondren@bcm.edu
832-355-9942

VOYAGER PAD

Vascular Outcomes Study of ASA along with Rivaroxaban in Endovascular or Surgical Limb Revascularization for Peripheral Artery Disease

Principal Investigator: Joseph Mills, MD (H-37075)
Principal Investigator: Eduardo Hernandez, MD (W-20150816)
Sponsor: Bayer Healthcare Pharmaceuticals

This international, multicenter, randomized, double-blind placebo controlled study will evaluate whether rivaroxaban added to acetylsalicylic acid (ASA) is superior to ASA alone in reducing the risk of major thrombotic vascular events in symptomatic PAD patients undergoing lower extremity revascularization procedure.

Main Inclusion Criteria:

1. Male or female over age 50 with symptomatic PAD with ischemic rest pain or ischemic ulceration
2. Anatomical imaging evidence of arterial occlusive disease below the inguinal ligament within 6 months prior to or at the time of the qualifying revascularization

Main Exclusion Criteria:

1. Patients undergoing revascularization for asymptomatic PAD or mild claudication without functional limitation of the index leg
2. Planned dual antiplatelet therapy (DAPT) use for the qualifying revascularization procedure of clopidogrel in addition to ASA for >30 days after the qualifying revascularization procedure

VOYAGER trial contacts:

Cherry Adjchavanich
(H-37075)
Adjchava@bcm.edu
713-798-7869

Gilberto De Freitas, RN
(W-20150816)
gilberto.defreitas@bcm.edu
832-355-4998

SHIELD II (H-37865)

Coronary Interventions in High-Risk Patients Using a Novel Percutaneous Left Ventricular Support Device

Principal Investigator: Andrew Civitello, MD **Sponsor:** St. Jude Medical

The HeartMate PHP System is a temporary (<6 hours) ventricular assist device indicated for use during high risk percutaneous coronary interventions (PCI) performed in elective or urgent, hemodynamically stable patients with severe coronary artery disease and depressed left ventricular ejection fraction. This is a prospective, randomized, multi-center, open-label trial of the HeartMate PHP at up to 60 sites in the US. Control device will be the Abiomed Impella® Recover® LP 2.5 Percutaneous Cardiac Support System.

Main Inclusion Criteria:

1. Patient is undergoing elective or urgent high risk PCI procedure and is hemodynamically stable
2. The presence of complex coronary artery disease (CAD) makes hemodynamic instability resulting from repeat episodes of reversible myocardial ischemia during PCI likely. Complex CAD is defined as:

   an ejection fraction of ≤35% AND at least one of the following:

   - intervention of the last patent coronary conduit, OR
   - intervention of an unprotected left main artery OR
3. an ejection fraction of ≤35% AND intervention on patient presenting with triple vessel disease defined as at least one significant stenosis (at least 50% diameter stenosis on visual assessment) in all three major epicardial territories

Main Exclusion Criteria:

1. Emergency PCI
2. Myocardial infarction at baseline
3. Cardiac arrest within 24 hours of procedure requiring CPR or defibrillation
4. Hemodynamic support with the HeartMate PHP post-PCI is anticipated
5. Cardiogenic shock (systolic blood pressure (SBP)) <90 mmHg for >1 hour with either cool clammy skin OR oliguria OR altered sensorium and cardiac index <2.2 L/min/m2)

SHIELD II contact:
Sree Vidya
css@bcm.edu
832-355-7019

EVOLVE SHORT DAPT (H-38901)

A prospective, multicenter, single-arm study designed to assess the safety of 3-month dual antiplatelet therapy (DAPT) in subjects at high risk for bleeding undergoing percutaneous coronary intervention (PCI) with a SYNERGY™ Everolimus-Eluting Platinum Chromium Coronary Stent System (SYNERGY Stent System)

Principal Investigator: Ali Mortazavi, MD **Sponsor:** Boston Scientific Corp.

The primary objective of the EVOLVE Short DAPT Study is to assess the safety of 3-month dual antiplatelet therapy (DAPT) in subjects at high risk for bleeding undergoing percutaneous coronary intervention (PCI) with the SYNERGY Stent System.

Subject is considered at high risk for bleeding, defined as meeting one or more of the following criteria at the time of enrollment:

1. ≥ 75 years of age and, in the opinion of the investigator, the risk of major bleeding associated with >3 months of DAPT outweighs the benefit
2. need for chronic or lifelong anticoagulation therapy
3. history of major bleeding (severe/life threatening or moderate bleeding based on the GUSTO classification) within 12 months of the index procedure
4. history of stroke (ischemic or hemorrhagic)
5. renal insufficiency (creatinine ≥2.0 mg/dl) or failure (dialysis dependent)
6. platelet count ≤100,000/µL

Main Exclusion:

1. Subject with an indication for the index procedure of acute ST elevation MI (STEMI)
2. Subject with implantation of a drug-eluting stent within 9 months prior to index procedure

EVOLVE Short DAPT:
Gilberto De Freitas, RN
gilberto.defreitas@bcm.edu
832-355-4998

ADAPT RESPONSE (H-38200)

AdaptivCRT® (aCRT) algorithm CRT devices in reducing incidence of the combined endpoint of all-cause mortality and intervention for heart failure decompensation compared to standard CRT therapy

Principal Investigator: John Seger, MD **Sponsor:** Medtronic, Inc.

The aCRT algorithm has been developed to provide RV-synchronized LV pacing when intrinsic AV conduction is normal or BiV pacing otherwise. The algorithm also adjusts AV and VV delays based on periodic automatic evaluation of intrinsic conduction intervals. The algorithm is intended to provide ambulatory CRT optimization and allow more physiologic ventricular activation and greater device longevity in patients with normal AV conduction by reducing unnecessary RV pacing.

Main Inclusion:

1. Sinus Rhythm at time of enrollment
2. Left Bundle Branch Block (LBBB) as documented on an ECG
3. Intrinsic, normal AV conduction as documented on an ECG by a PR interval less than or equal to 200ms
4. Left ventricular ejection fraction less than or equal to 35%
5. NYHA class II, III or IV despite optimal medical therapy

Main Exclusion:

1. Subject has unstable angina, or experienced an acute myocardial infarction (MI) or received coronary artery revascularization (CABG) or coronary angioplasty (PTCA) within 30 days prior to enrollment
2. Subject is post heart transplant (subjects on the heart transplant list for the first time are not excluded)

ADAPT RESPONSE contact:

Melyssa Fink
mfink@bcm.edu
832-355-3710

Portico™ Re-sheathable Transcatheter Aortic Valve System US IDE Trial (H-33836)

Designed to evaluate the safety and effectiveness of the SJM Portico™ Re-sheathable Transcatheter Heart Valve and Delivery Systems via transfemoral and alternative delivery for patients with severe aortic stenosis.

Principal Investigator: Joseph Coselli, MD **Sponsor***:* St. Jude Medical

This is a randomized trial to evaluate the safety and effectiveness of the Portico™ Re-Sheathable Transcatheter aortic valve system. The trial will include approximately 908 randomized subjects at up to 70 investigational sites to analyze the high risk cohort and extreme risk cohort together against a commercially available control for the primary safety and effectiveness endpoints.

Main Inclusion:

1. Documented diagnosis of symptomatic severe aortic stenosis with echocardiographically derived criteria: mean gradient > 40 mmHg or jet velocity greater than 4.0 m/s or Doppler Velocity Index <0.25 and an initial aortic valve area (AVA) of < 1.0 cm2 (indexed EOA < 0.6 cm2/m2)
2. Predicted risk and operative mortality is ≥ 15% or a minimum STS score of 8%. A candidate who does not meet the STS criteria can be included in the study if two surgeons conclude that the patient's predicted risk of operative mortality is ≥15%

Main Exclusion:

1. Pre-existing prosthetic heart valve or other implant in any valve position, prosthetic ring, severe mitral annular calcification (MAC), or severe (greater than 3+) mitral insufficiency (subjects with pre-existing surgical bioprosthetic aortic heart valve should be considered for the Valve-in-Valve registry
2. Untreated clinically significant coronary artery disease requiring revascularization
3. Renal insufficiency (creatinine > 3.0 mg/dl) and/or end stage renal disease regarding chronic dialysis

PORTICO contact:

Jennifer Parenti
jparenti@texasheart.org
832-355-9301