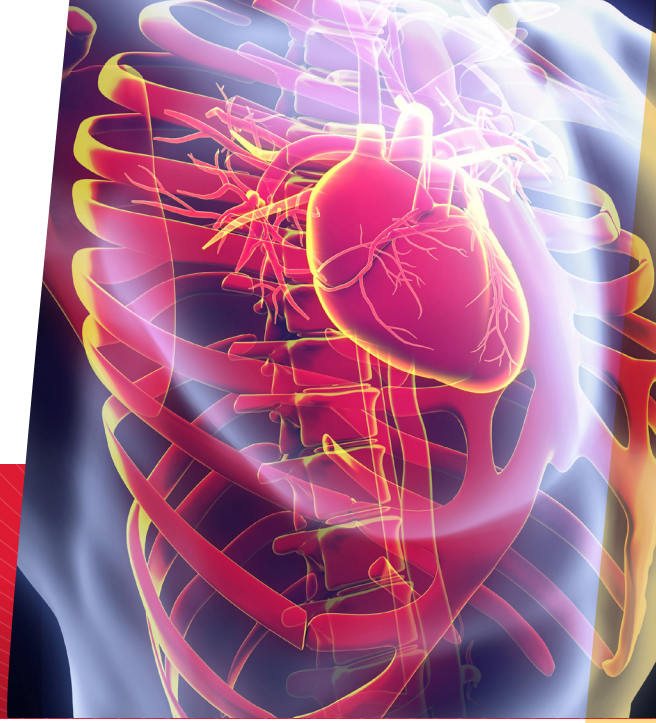
CHI St. Luke's Health

Baylor St. Luke's Medical Center

in partnership with

Baylor College of Medicine

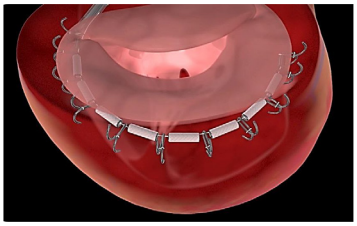
Texas Heart® Institute



Cardiology Research Newsletter

Fall 2016 • Issue Six

Percutaneous Approach to Correct Functional Mitral Regurgitation



AccuCinch® Ventriculoplasty System

The AccuCinch clinical trial is an early feasibility study designed to assess the safety and performance of the AccuCinch® Ventriculoplasty System. This device treats patients with symptomatic functional mitral regurgitation and left ventricular remodeling due to dilated cardiomyopathy. To be considered for the trial, patients should have stable symptoms on guideline-directed medical therapy and be of high operative risk.

The study device is comprised of the implant, access system, and delivery system. The implant (shown above) includes nitinol eyelet anchors, multiple discrete force distribution members (FDMs), lock, and a cinch cable. The catheter is placed through the left ventricle and can deploy up to 15 anchors along the ventricular surface of the posterior mitral annulus. A cable is run through the anchors, which can be tensioned to create posterior plication.

Guilherme Silva, MD (third to the right), Medical Director, Structural Heart Program and Principal Investigator of the AccuCinch trial at Baylor St. Luke's, is pictured with staff from the heart failure clinic.

The AccuCinch trial plans to enroll 15 patients from up to five centers in the U.S., including Baylor St. Luke's Medical Center, NYU Langone Medical Center, Intermountain Medical Center, University of Washington Medical Center, and NewYork-Presbyterian/Columbia University Medical Center.

Eligibility for Patient Screenings

1. Severity of FMR: ≥ moderate (i.e. ≥ 2+, according to 2003 ASE Guidelines for grading mitral regurgitation)
2. Ejection fraction: ≥ 20 to ≤ 60%
3. Symptom status: NYHA II-IVa (i.e. ambulatory)
4. No prior surgical, transcatheter, or percutaneous mitral valve intervention

Contact

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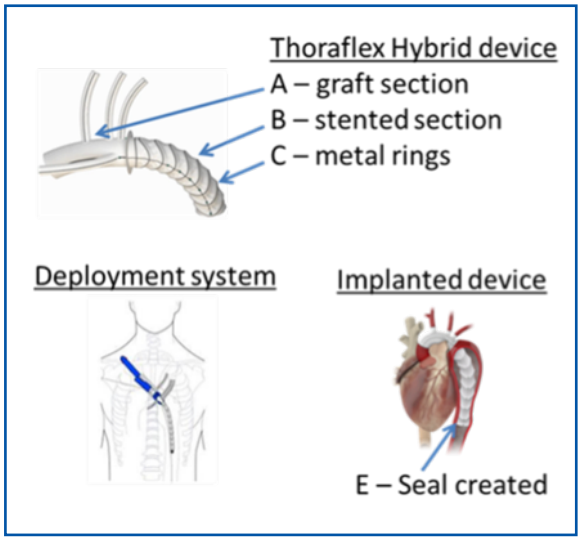
Thoraflex™ Hybrid IDE Study

Baylor St. Luke's will perform a study to assess the effectiveness and safety of the Thoraflex™ Hybrid Device to treat aortic disease affecting the aortic arch and descending aorta, with or without involvement of ascending aorta.

The study will also assess safety and early clinical outcomes in patients who receive an extension procedure within one year of Thoraflex™ Hybrid Device implantation.

Lastly, the study will assess the safety and clinical outcomes of patients who receive a Thoraflex™ Hybrid to treat a ruptured aorta. Patients will be followed for three years. The primary endpoint will be freedom from defined major adverse events (MAE) occurring ≤ 1 year post-procedure.



Vascutek Ltd, a Terumo Company, developed the Thoraflex™ Hybrid Device (Plexus™ 4 and Ante-Flo™) for open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta, with or without involvement of the ascending aorta, in cases of aneurysm and/or dissection.

The Thoraflex™ Hybrid Device may be considered a development of the elephant trunk (ET) grafts, with the addition of a stented distal section. In some cases, this will allow a single stage procedure to be carried out, depending on the length of affected vessel. As the device is fully sealed and has a collar to aid anastomosis, it removes the requirement for in-situ sealing and the suturing together of two devices, thereby reducing cardiopulmonary bypass (CPB) time and overall procedure time.

By reducing the procedure time and negating the need for as many subsequent procedures, this method could greatly improve the success of this procedure and improve patient outcomes.

The ability to treat complex anatomies in addition to reducing procedure and CPB time justify the investigation of the Thoraflex™ Hybrid Device. Safety and effectiveness data for subjects treated with the Thoraflex™ Hybrid Device will be compared to historical data from subjects treated using standard ET surgical repair.

We anticipate that up to 83 patients will be recruited over a 14-month period. Patients will be evaluated at the following time points: pre-procedure, implant, discharge/30 days, three months, 12 months, 24 months, and 36 months. An additional visit may be needed for patients who undergo an extension procedure within one year of Thoraflex™ Hybrid Device implantation.

Sixty five patients will be recruited to the primary study group (maximum 12 per site). An additional group of patients (up to 18 across all sites) with a ruptured aorta may also be recruited.

A historical control population has been derived from a comparable patient population who received treatment for thoracic aortic disease using the current standard of care, which is the conventional (two-stage) elephant trunk technique. Using data from the comparator population, a performance goal target is set at 57.4 percent.

The study will be deemed a success if the lower limit of the 95 percent confidence interval associated with the proportion of study patients free from the defined composite major adverse events (permanent stroke, permanent paraplegia/paraparesis, unanticipated aortic related re-operation and all-cause mortality) at one year post procedure is greater than 57.4 percent.

Only patients included in the main study group will be included in the performance goal analysis; patients recruited into the additional aortic rupture group will not be included in the primary endpoint analysis. All patients in the main study group will be included in the analysis regardless of whether or not an extension procedure was performed.

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New in STEM Cell

CONCERT-HF

Combination of mesenchymal and C-kit+ cardiac stem tells as regenerative therapy for heart failure.

This is a Phase II, randomized, placebo-controlled clinical trial to evaluate heart function and in four groups of patients. It includes those treated with:

- Only their own bone marrow cells
- Only their own heart tissue cells
- A combination of their own bone marrow and heart tissue cells
- A placebo

All patients will be followed for one year.

Main Inclusion Criteria

- Be ≥ 21 and <80 years of age
- Have documented coronary artery disease (CAD) with evidence of myocardial injury, LV dysfunction, and clinical evidence of HF
- Have an EF ≤ 40% by cMRI
- Have New York Heart Association (NYHA) class II or III heart failure symptoms

Main Exclusion Criteria

- Indication for standard-of-care surgery (including valve surgery, placement of left-ventricular assist device, or heart transplantation), coronary artery bypass grafting (CABG) procedure, and/or percutaneous coronary intervention (PCI) for the treatment of ischemic and/or valvular heart disease
- Valvular heart disease, including mechanical or bioprosthetic heart valve or moderate to severe (any valve) insufficiency/ regurgitation within 12 months of consent

SENECA

A Phase I, first-in-human, multicenter, randomized, double-blinded, placebo-controlled study of the safety and efficacy of allogeneic mesenchymal stem cells in cancer survivors with anthracycline-induced cardiomyopathy.

The primary purpose of this study is to examine the safety and feasibility of delivering allogeneic human mesenchymal stem cells (allo-MSCs) by transendocardial injection to cancer survivors with left ventricular (LV) dysfunction secondary to anthracycline-induced cardiomyopathy (AIC).

Main Inclusion Criteria:

- Be ≥ 18 and < 80 years of age
- Be a cancer survivor with diagnosis of AIC
- Have an LVEF ≤ 40 percent by cMRI
- Be in NYHA class II-III
- Have a period of at least two years of clinical cancer-free state and low likelihood of recurrence (a five-year risk of recurrence estimated at 30 percent or less), as determined by an oncologist, based on tumor type, response to therapy, and negative meta static work-up at the time of diagnosis

All patients will be followed for one year.

Main Exclusion Criteria

- A life expectancy <12 months
- A CT scan or baseline cardiac MRI showing new tumor or suspicious lymphadenopathy raising concern of malignancy
- Presence of CAD as determined via imaging within 12 months prior study enrollment (e.g. a rest and stress nuclear scan (SPECT/ PET/CT), a stress echocardiogram, stress MRI, or cardiac computed tomography angiography (CCTA). If coronary arteriogram, within the last 24 months)

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Baylor St. Luke's First in Houston to Offer AMAZE Clinical Trial

September is Atrial Fibrillation Awareness Month and Dr. Abdi Rasekh, Baylor St. Luke's Arrhythmia Center Medical Director, recently went on Fox 26 morning news to discuss the risks factors and current treatment for this complex condition.

Atrial fibrillation (AFib) is the most common sustained tachyarrhythmia and can be a major risk factor for stroke. The CDC estimates that in the U.S. alone, AFib is responsible for more than 130,000 deaths a year and about $6 billion a year in health care costs. Current data suggests that a single ablation procedure of the pulmonary veins for treating persistent or long-standing persistent AFib results in success rates between 20 to 40 percent.

However, the left atrial appendage (LAA) is a known trigger of AFib, but is rarely isolated due to risks of ablating this fragile structure as well as thrombus formation in an isolated appendage even in normal sinus rhythm. The LARIAT+® Suture Delivery System is a permanent, non-implant solution to LAA closure that provides complete closure and electrical isolation of the LAA without the risks associated with ablation, thus eliminating a potential source of AFib

The AMAZE randomized superiority trial focuses on demonstrating that uses the LARIAT+® for LAA closure. Pulmonary vein isolation (PVI) catheter ablation will lead to a reduced incidence of recurrent AFib when compared to PVI alone (the current standard treatment).

The AMAZE trial is currently open for patients with symptomatic persistent or longstanding persistent AFib. Baylor St. Luke's, the only AMAZE trial site in the greater Houston area, has randomized 11 subjects out of 28 patients presented to the screening committee.

Patient Eligibility Requirements

1. Documented diagnosis of symptomatic persistent or longstanding persistent non-valvular AFib:
   - Persistent AFib is defined as: AFib sustained for ≥ 7 days and ≤ 1 year
   - Longstanding Persistent is defined as: continuous AFib for > 1 year duration
   - Non-valvular AFib is defined as: cases without a mechanical heart valve requiring anticoagulation or without moderate to severe mitral stenosis
2. Failed at least one class I or III AAD
3. Have no prior epicardial or endocardial AFib ablation procedure

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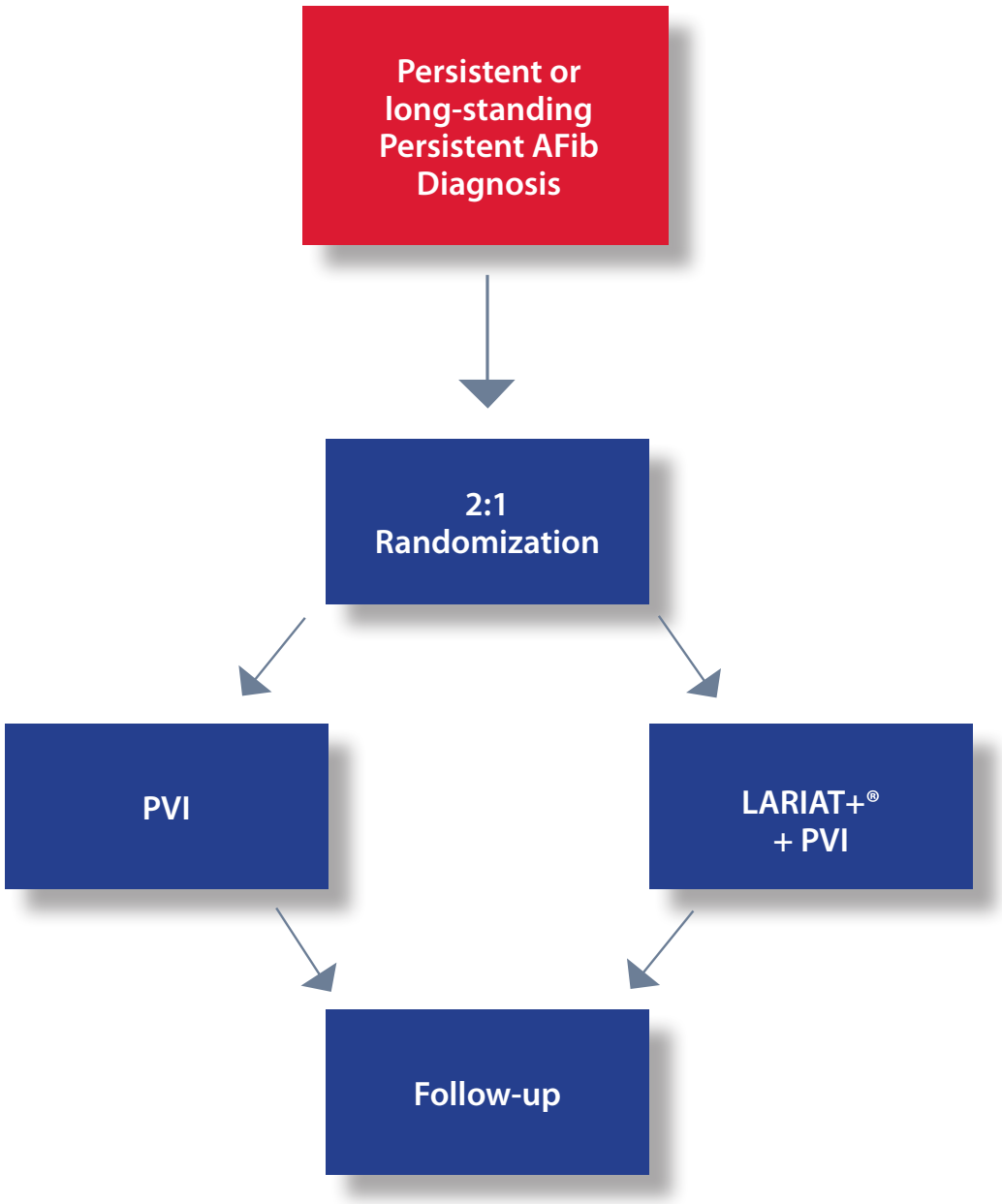

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