2017 Cardiology Clinical Trials

Is your patient a candidate for a clinical trial?

Referring your patient
The UPMC Heart and Vascular Institute is a leader in conducting research studies and clinical trials to better understand and treat cardiovascular disease.

To refer a patient, please call 1-84-HVI-TRIAL (844-848-7245) or email HViresearch@upmc.edu.

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Cardiac Catheterization

ABSORB III/IV: Prospective, randomized (1:1, Absorb BVS to XIENCE), single-blind, multicenter clinical evaluation of Absorb BVS (the Everolimus Eluting Bioresorbable Vascular Scaffold) in the treatment of subjects with de novo native coronary artery lesions to evaluate the incidence of angina occurring within one year and to evaluate long-term clinical outcomes of Absorb BVS compared to XIENCE in the treatment of subjects with ischemic heart disease.

Inclusion criteria:
- Evidence of myocardial ischemia (silent ischemia, UA or stable angina, NSTEMI or recent STEMI);
- up to three de novo coronary artery lesions in a max of two epicardial vessels; %DS of ≥ 50% and < 100%, with a TIMI flow of ≥ 1, and one of the following: stenosis ≥ 70%, an abnormal functional test (e.g., FFR ≤ 0.80 and/or a positive stress test), or presentation with ACS; RVD by visual estimation of ≥ 2.50 mm and ≤ 3.75 mm; length by visual estimation of ≤ 24 mm.

Principal Investigator: Catalin Toma, MD

DREAM-HF: Double-blind, randomized, sham-procedure-controlled study to determine whether transcendocardial delivery of 150 million (M) allogeneic human bone marrow derived MPCs (CEP-41750) administered during a single cardiac catheterization with intracardiac mapping is more effective than a scripted sham procedure in patients with chronic heart failure due to LV systolic dysfunction of either ischemic or non-ischemic etiology.

Inclusion criteria:
- Age 18-80 with diagnosis of chronic HF of ischemic or non-ischemic etiology for at least six months before the initiation of screening procedures, NYHA Class II-III symptoms, on stable and optimally tolerated dosages of heart failure therapies without change in dose for at least one month before study intervention; LVEF ≤ 40% by 2-D echo. Not on anticoagulation.

Principal Investigator: Marc Simon, MD

Primary Interventional Cardiologist: Catalin Toma, MD

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AMI MultiStem®: Phase II prospective, randomized, double-blind, sham-controlled, parallel-group, multicenter trial designed to assess the safety of AMI MultiStem® in subjects with NSTEMI; AMI MultiStem® vial product is a cell therapy investigational product originating from adherent adult stem cells taken from the bone marrow of a non-related donor and expanded ex-vivo. MultiStem® will be delivered by a micro-infusion catheter into the adventitial layer of the target vessel following successful PCI.

Inclusion criteria: Age 18 or older, diagnosis of NSTEMI scheduled to undergo cardiac catheterization within 3 days, peak CK-MB > 3X ULN or peak troponin > 3X ULN, female subjects who are either not pregnant, not breastfeeding, and not planning on becoming pregnant during the study, and not of childbearing potential, male subjects must agree to use an adequate method of contraception and must agree to not donate sperm from the time of investigational procedure through Day 90, subject must undergo an echo or LV-gram and have an LVEF > 20% with regional wall motion abnormality corresponding to the vascular territory of the suspected culprit coronary lesion, undergo successful PCI, confirm the NSTEMI was due to obstructive atherosclerotic disease.

Principal Investigator: Catalin Toma, MD

COAPT: Prospective, randomized, parallel-controlled clinical evaluation of the safety and effectiveness of the MitraClip® System for the treatment of functional mitral regurgitation in symptomatic heart failure subjects who are treated per standard of care and who have been determined by the site’s local heart team as not appropriate for mitral valve surgery. Eligible subjects will be randomized in a 1:1 ratio to the MitraClip® device (device group) or to no MitraClip® device (control group).

Inclusion criteria: Symptomatic functional MR (> 3+) of either ischemic or non-ischemic origin, not a surgical candidate, NYHA Class II, III, or ambulatory IV, (LVEF) is ≤ 20% and ≤ 50%, heart failure hospitalization in past 12 months and/or corrected BNP ≥ 300 pg/ml within 90 days of enrollment.

Principal Investigator: Conrad Smith, MD

COMPLETE: Randomized, comparative effectiveness study of complete vs. culprit-only revascularization strategies to treat multivessel disease after primary PCI for STEMI.

Inclusion criteria: Men and women within 72 hours after successful PCI to the culprit lesion for STEMI; multivessel disease defined as at least one additional non-infarct related coronary artery lesion that is at least 2.5 mm in diameter that has not been stented as part of the primary PCI and that is amenable to successful treatment with PCI and has at least 70% DS or at least 50% DS with fractional flow reserve (FFR) ≤ 0.80.

Principal Investigator: Catalin Toma, MD

SPECT vs. FFR: Simultaneous assessment of invasive FFR and SPECT myocardial ischemia using regadenoson in the catheterization lab. The aim is to determine the correlation between FFR and the presence or extent of associated ischemia in patient with CAD.

Inclusion criteria: Age 18 or older scheduled to undergo cardiac catheterization.

Principal Investigator: Prem Soman, MD

ALIVE: Clinical Study of the BioVentrix Revivent TC™ System for Treatment of Left Ventricular Aneurysms: A prospective, multicenter, dual-arm pivotal study of 126 patients with 2:1 study (84 patients treated with the investigational device) vs. active concurrent control group (42 patients). The Revivent TC™ System is indicated for patients referred for surgical treatment of left ventricular aneurysm or anterior scar that is contiguous, and includes both anterior and septal components.

Inclusion Criteria: Age 18-80; CHF patients suffering from heart failure symptoms as defined by NYHA Class > 2 not responsive to medical therapy, with LVEF < 45%, LVESV ≥ 50 mL/m2; presence of LV aneurysm or anterior scar; defined by a contiguous acountactile (akinetic and/or dyskinetic) scar involving the septum and anterior, apical, or anterolateral regions of the LV as evidenced by cardiac imaging and referred for surgical management; viability of myocardium in regions remote from area of intended scar exclusion as evidenced by cardiac imaging; patient is on adequate guideline-directed medical therapy; candidates allocated to active concurrent control group must meet all inclusion criteria (including LV aneurysm scar presence), with the exception of LV aneurysm scar location.

Principal Investigator: Catalin Toma, MD

Sub-Investigators: Marc Simon, MD
Christopher Sciortino, MD

FLARE: Prospective, single-arm, controlled, multicenter study of the FlowTriever® System to evaluate the safety and effectiveness of the FlowTriever® System for use in the removal of emboli from the pulmonary arteries in the treatment of acute pulmonary embolism (PE).

Inclusion criteria: Age 18-75, clinical signs, symptoms, and presentation consistent with acute PE, PE symptom duration ≤ 14 days, CTA evidence of proximal PE (filling defect in at least one main or lobar pulmonary artery), RV/LV ratio of ≥ 0.9 (Note: enrollment qualification assessment based on investigator’s interpretation of RV/LV ratio at baseline; CoreLab results are not available until after the 48 hour CTA), systolic blood pressure ≥ 90 mmHg (initial SBP may be ≥ 80 mmHg if the pressure recovers to ≥ 90 mmHg with fluids), stable heart rate < 130 BPM prior to procedure.

Principal Investigator: Catalin Toma, MD

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THEME: Multicenter, prospective observation registry. By collecting prospective descriptive data, this study aims to provide insight into disease-defining characteristics resulting in the clinical decision to use the TandemHeart System for mechanical support and enhance knowledge of best practice regarding clinical management, weaning/exit strategies.

Inclusion criteria: Sinus rhythm with LBBB, and must include: intrinsic QRS duration U 140ms (men) and U 130ms (women), QS or rS in leads V1 and V2, and notching or slurring in U 2 leads V1,V2,V5,V6, I, and aVL. Normal AV conduction, left ventricular ejection fraction M 35% and NYHA Class of II, III, or IV.

Exclusion criteria: less than 18 years of age, permanent atrial arrhythmias, receiving or has received cardiac resynchronization therapy, has unstable angina or experienced an acute myocardial infarction, received CABG or PTCA within 30 days of enrollment, has a mechanical tricuspid heart valve or scheduled for valve repair or replacement, is post heart transplant, has limited life expectancy, cannot remain available for two years of follow-up, is enrolled in another clinical trial, or is pregnant.

Principal Investigator: Catalin Toma, MD

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

Inclusion Criteria: Age 18 or older, considered at high risk for bleeding, must have had implantation of at least one SYNERGY stent within the preceding three calendar days, must be able to take study-required antiplatelet therapy (as required per protocol), is willing to comply with all protocol requirements, including agreement to stop taking P2Y12 inhibitor at the three-month milestone, if eligible per protocol.

Principal Investigator: Saul Silver, MD
Sub-Investigator: Catalin Toma, MD

Cardiac Imaging

ADMIRE – HCM: Prospective, observational cohort study of all patients with hypertrophic cardiomyopathy undergoing clinical cardiac MRI at UPMC Presbyterian. Participants will undergo research blood draw as well as additional research MRI imaging at the time of the study. Participants will be followed longitudinally to determine the association between imaging findings and heart outcomes such as rhythm disturbance and mortality. If selected, eligible participants will be potentially eligible for follow up cardiac MRI (and/or other imaging) the costs of which will be covered by research funding.

Principal Investigator: Tim Wong, MD, MS

TOPAS III: Prospective study to develop and validate new parameters and biomarkers to improve the assessment of stenosis severity and myocardial impairment, the risk stratification, and the clinical decision making in patients with low-flow low-gradient aortic stenosis and to assess the impact of the different therapeutic strategies on outcomes.

Inclusion criteria: Age > 21 years, suspected severe AS defined by an AVA ≤ 1.0 cm2 and indexed AVA ≤ 0.6 cm2/m2, low-gradient defined by a mean gradient < 40 mmHg, low LV outflow defined by a stroke volume index ≤ 35 mL/m2.

Principal Investigator: João Cavalcante, MD

CLASS CMR: Multicenter prospective CoreValve® Evolut R study of paravalvular leak assessment using cardiac MRI for assessment of its impact on LV reverse remodeling and cardiovascular outcomes.

Inclusion criteria: Age 60 and older, has undergone commercial TAVR implant with Evolut R within prior 25 days to eight weeks, patient has ≥ mild PVL on TTE study performed at approximately the one month post-TAVR (regular clinical follow-up visit).

Principal Investigator: João Cavalcante, MD

Electrophysiology

AdaptResponse: Clinical study testing 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 atrio-ventricular (AV) conduction and left bundle branch block (LBBB).

Inclusion criteria: Sinus rhythm with LBBB, intrinsic QRS duration ≥ 140ms (men) and ≥ 130ms (women), notching or slurring in leads V1,V2,V5,V6, I, and aVL. Normal AV conduction, ejection fraction ≥ 35% and NYHA Class of II, III, or IV.

Principal investigator: Evan Adelstein, MD

Leadless II: Study evaluating the safety and effectiveness of the leadless pacemaker system in treating patients with a slow heart rate or irregular heartbeats. This study is intended to help reduce certain complications associated with traditional pacemakers.

Inclusion criteria: Chronic and/or permanent atrial fibrillation with 2° or 3° AV or bifascicular bundle branch block (BBB block), including slow ventricular rates. Normal sinus rhythm with 2° or 3° AV or BBB block and a low level of physical activity or short expected lifespan. Sinus bradycardia with infrequent pauses or unexplained syncope with EP findings.

Principal Investigator: Sandeep Jain, MD

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PSR (Product Surveillance Registry): Post-market surveillance registry to obtain information on product performance assessment. The objective of the registry is to serve as an ongoing source of acute and chronic product performance, patient safety, and clinical outcomes information associated with the use of market-released products.

Inclusion criteria: Patient has or intends to receive or be treated with an eligible Medtronic product.

Principal Investigator: Sandeep Jain, MD

Acute Mechanical Response to Antiarrhythmic Drug Therapy (AA and CRT): Study to determine if drugs with a sodium channel-blocking mechanism exert a detrimental electromechanical effect on cardiac function in patients depending upon baseline intraventricular conduction and left ventricular function.

Inclusion criteria: Implanted cardiac device requiring generator change and new device. Able to sign informed consent.


Principal investigator: Evan Adelstein, MD

UNTOUCHED: Global, multisite, prospective, non-randomized study that will enroll subjects eligible for implantation with a de novo EMBLEM S-ICDTM System. Devices will be programmed with zone cut-offs at 200 bpm (Conditional Shock Zone) and 250 bpm (Shock Zone).

Inclusion criteria: Age ≥ 21 years, an indication for primary prevention of sudden cardiac death, LVEF ≤ 35%.

Exclusion criteria: History of spontaneous VT or VF, bradycardia pacing indication, NYHA Class IV, previous pacemaker or defibrillator, receiving hemodialysis.

Principal Investigator: Samir Saba, MD

aMAZE (Left Atrial Appendage Ligation with the LARIAT® Suture Delivery System as Adjunctive Therapy to Pulmonary Vein Isolation for Persistent or Longstanding Persistent Atrial Fibrillation): Prospective, multicenter, randomized (2:1) controlled study to evaluate the safety and effectiveness of the LARIAT® Suture Delivery System to ligate the left atrial appendage (LAA) in adjunct with a planned PVI to treat patients with symptomatic persistent or longstanding persistent atrial fibrillation. Clinicaltrials.gov identifier: NCT02513797; aMAZE is an FDA-approved trial - U.S. FDA IDE#G150103.

Inclusion criteria: Age 18-80 with documented symptomatic persistent or longstanding persistent non-valvular atrial fibrillation, persistent AF sustained for ≥ 7 years and ≤ 1 year, longstanding persistent AF > 1 year duration, failed at least one class I or III AAD.

Exclusion criteria: Prior ablation, prior procedure which involved opening pericardium/pericardial space, or prior thoracic radiation, NYHA Class IV or EF < 30%, stroke, MI, or unstable angina within three months prior to planned study intervention.

Principal Investigator: Raveen Bazaz, MD

INVESTED (INfluenza Vaccine to Effectively Stop Cardio Thoracic Events and Decompensated heart failure): Multicenter trial to assess the cardiopulmonary benefit of high versus standard-dose influenza vaccine in a high risk cardiovascular patients. The influenza infection is known to be associated with an increased risk of major cardiovascular events, and the vaccine is widely underutilized in this population. This is a double blind study and patients will be randomized to either the high or standard dose influenza vaccine.

Inclusion criteria: Age 18 or older with a documented history of at least one of the following: hospitalization for spontaneous MI (within one year of the base line visit), hospitalization for heart failure (within two years of baseline visit). Subjects also must have at least one of the following secondary criteria: prior MI (for subjects qualifying based on heart failure admission, or an MI prior to the qualifying MI), age 65 or older, current or historical ejection fraction of < 40%, documented diagnosis of type I or type II diabetes mellitus, current BMI ≥ 30, documented history of renal impairment (eGFR < 61 for at least two readings in the past year), history of ischemic stroke, history of peripheral artery disease, current tobacco smoker.

Principal Investigator: Jared Magnani, MD