2018 Heart Failure and Pulmonary Hypertension 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 heart failure and pulmonary hypertension.

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

For more information about the UPMC Heart and Vascular Institute, please call 1-855-UPMC-HVI (876-2484) or visit UPMC.com/HVI.

Heart Failure

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 acontractile (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

COAPT Continued Access Study: Prospective, multicenter, single arm, continued access registry to evaluate the MitraClip® NT System for the treatment of clinically significant 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.

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, national Medicare coverage by CMS.

Principal Investigator: Conrad Smith, MD
DREAM-HF: Double-blind, randomized, sham-procedure-controlled study to determine whether transcatheter delivery of 150 million (M) allogeneic (i.e., from a volunteer adult donor) human bone marrow derived mesenchymal precursor cells (MPCs) administered during a single cardiac catheterization with intracardiac mapping is more effective than a sham procedure (i.e., control) in patients with chronic heart failure due to LV systolic dysfunction of either ischemic or non-ischemic etiology who have received optimal medical and coronary revascularization therapy, and to evaluate the safety and tolerability of transcatheter delivery of MPCs in this patient population.

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; at least 1 hospitalization for heart failure >1 month but <9 months, OR at least 1 outpatient visit requiring IV therapy for heart failure >1 month but <9 months, OR NT-proBNP >1000 pg/mL or >1200 pg/mL for patients with atrial fibrillation.

Principal Investigator: Marc Simon, MD
Primary Interventional Cardiologist: Catalin Toma, MD

GALACTIC-HF: Double-blind, randomized, placebo-controlled, multicenter study to assess the efficacy and safety of omecamtiv mecarbil on morbidity in subjects with chronic heart failure with reduced ejection fraction.

Inclusion criteria: Males or females age 18 and older who have a diagnosis of chronic heart failure, currently on stable medications who have been hospitalized in the last year for heart failure.

Exclusion criteria: Inability to attend regular clinic visits, receiving IV nitroprusside, on chronic antiarrhythmic medications other than amiodarone, digoxin, calcium channel blocker, and beta-blockers.

Principal Investigator: Marc Simon, MD

Oral Nitrite for Fatigability in HFrEF: Double-blind, randomized controlled trial of 20-40 mg oral sodium nitrite (capsules) for 4 weeks duration. Pre- and post-drug testing includes functional evaluation, MRI spectroscopy, muscle biopsy, optional right heart cath for central cardiac performance measures.

Inclusion Criteria: Age ≥ 70 years, EF > 40%, diagnosis of HFrEF by prior diagnosis of HF via one of these: medical record diagnosis by attending cardiologist, verbal confirmation of HFrEF with attending cardiologist or PI review of medical record to confirm HFrEF.

Principal Investigator: Daniel E. Forman, MD

VICTORIA: Vericiguat global study in subjects with heart failure and reduced ejection fraction.

Primary inclusion criteria: Male or female age 18 and older, history of chronic heart failure (EF <45%, NYHA II-IV) on standard heart failure therapy with a hospital admission for heart failure in the past six months.

Primary exclusion criteria: Currently prescribed long-acting nitrates, isosorbide or nitroglycerin patch, PDE5 inhibitors, sGC stimulators, is awaiting heart transplantation, or is receiving IV nitroprusside.

Principal Investigator: Marc Simon, MD

REDUCE LAP-HF II: Study to evaluate the clinical efficacy and safety of the investigational InterAtrial Shunt Device (IASD®) System II for patients with elevated left atrial pressure who remain symptomatic despite appropriate medical management. Placed by an interventional cardiologist during a standard catheter-based procedure, the IASD system II creates a very small opening between the left and right atria. This opening allows blood to flow from the high pressure left atrium to the low pressure right atrium. This redistribution of blood to the right side potentially reduces the pressure in the left side and in the lungs.

Primary Inclusion Criteria: Symptoms of HF requiring current treatment with diuretics for > 30 days Age > 40 years old, LV ejection fraction (EF) >40% within the past 6 months, without previously documented EF <30% (within the past 5 years)

Primary Investigator: Marc Simon, MD

Pulmonary Hypertension

REPAIR Trial: Prospective, multicenter, single-arm, open-label, Phase IV study of the effects of macitentan on right ventricular remodeling in pulmonary arterial hypertension assessed by cardiac magnetic resonance imaging.

Inclusion criteria: Males or females age 18-75, diagnosis of WHO Group 1 pulmonary arterial hypertension, on a stable dose of PAH-specific therapy for a least three months, or treatment naive males and females of childbearing age agree to use medically acceptable method of contraception.

Exclusion criteria: Pregnant or breastfeeding females, weigh less than 88 lbs., BMI greater than 35, recently started or planning to start cardiopulmonary rehab, history of pulmonary embolism or deep vein thrombosis, uncontrolled diabetes, cancer, need dialysis, moderate to severe lung disease, claustrophobia.

Principal Investigator: Marc Simon, MD

RAPAMYCIN: Phase 1 clinical trial of ABI-009, an mTOR inhibitor, for patients with severe pulmonary hypertension. Subjects will receive IV infusion weekly for 16 weeks to evaluate maximum tolerated dose and safety.

Inclusion criteria: WHO Group 1 PAH, functional class III, on two or more standard PAH therapies.

Principal Investigator: Marc Simon, MD

QCC374X2201 is a study investigating whether the experimental drug QCC374 is safe and has beneficial effects in people who have Pulmonary Arterial Hypertension (PAH). PAH is a progressive disease caused by narrowing or tightening (constricting) of the pulmonary arteries, which connect the right side of the heart to the lungs. The purpose of the study is to determine if QCC374 will lower high pressures in the pulmonary blood vessels in patients with PAH. QCC374 is an inhaled prostacyclin receptor (IPR) agonist and is taken in addition to other therapies for PAH.

Inclusion criteria: Group 1 PAH
Exclusion criteria: Current use of a prostacyclin analog or IPR agonist (epoprostenol, treprostinil, iloprost, beraprost or selexipag)

Principal Investigator: Marc Simon, MD