

2019 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 **1-844-848-7425 (1-84-HVI-TRIAL)** or email HVIresearch@upmc.edu.

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

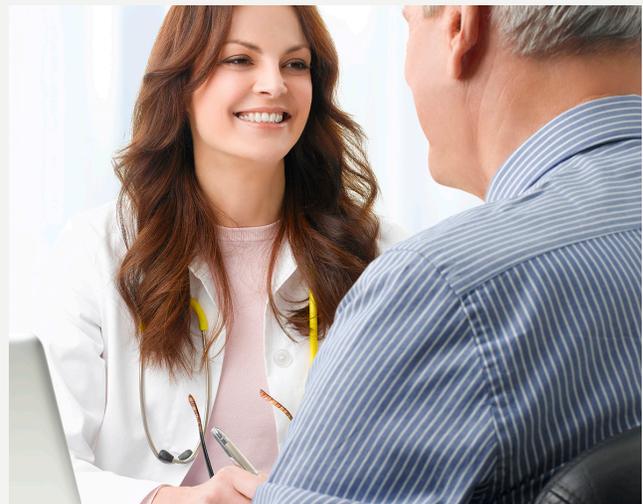
Cardiology

FlowTriever® All-Comer Registry for Patient Safety and Hemodynamics (FLASH)

A prospective, single-arm, multicenter study of FlowTriever® Retrieval/Aspiration System for submassive and massive pulmonary embolism. The use of the device will be assessed in a real-world population, with eligibility criteria that closely approximate its use in clinical practice. The FlowTriever System is cleared for the treatment of PE under 510(k) number K180466.

Inclusion criteria: Age \geq 18 years, clinical signs and symptoms consistent with acute PE, CTPA or pulmonary angiographic evidence of proximal filling defect in at least one main or lobar pulmonary artery, scheduled for PE treatment with the FlowTriever System per the Investigator's discretion.

Principal Investigator: Catalin Toma, MD



ILUMIEN IV: OPTIMAL PCI

Prospective, single-blind clinical investigation randomizing subjects to OCT-guided coronary stent implantation vs. angiography-guided coronary stent implantation; The objective is to demonstrate the superiority of an OCT-guided stent implant strategy in achieving larger post-PCI lumen dimensions and improving clinical cardiovascular outcomes in patients with high-risk clinical characteristics (diabetes mellitus) and/or with high-risk angiographic lesions (defined below).

Inclusion Criteria: Age $>$ 18, evidence of myocardial ischemia (e.g., stable angina, silent ischemia, unstable angina, or NSTEMI) suitable for elective PCI, planned use of XIENCE stent implantation during a clinically indicated PCI procedure, with at least one target lesion meeting high-risk criteria (e.g. culprit NSTEMI lesion, length \geq 28mm, bifurcation to be treated with 2 stents, severe calcification, etc.).

Principal Investigator: Catalin Toma, MD

Sub-Investigator: Jeffrey Fowler, DO

PK Papyrus: Coronary Covered Coronary Stent System

Approved by the FDA, under a Humanitarian Device Exemption (HDE H170004), the PK Papyrus Covered Coronary Stent System (HUD# 15-0343) is a Humanitarian Use Device for use in the treatment of acute perforations of native coronary arteries and coronary bypass grafts in vessels 2.5 to 5.0 mm in diameter.

Principal Investigator: Suresh Mulukutla, MD

The "RADIANCE II" Pivotal Study

A randomized clinical trial evaluating safety and efficacy of the ReCor Medical Paradise® System, a catheter-based system that delivers ultrasound energy to thermally ablate and disrupt the renal efferent and afferent sympathetic nerves while sparing the renal arterial wall, for patients with Stage II HTN. The objective is to achieve a reduction in sympathetic over-activity with the resultant effect of reducing systemic arterial BP and mitigating resultant end organ damage.

Inclusion Criteria: M/F ages 18-75 with documented diagnosis of stage II HTN, taking 0-2 anti-HTN medications at time of consent, average blood pressure readings of greater than or equal to 140/90 and less than or equal to 180/120, suitable renal anatomy by CTA/MRA, Sinus rhythm at time of procedure.

Exclusion Criteria: No history of treatment with anti-HTN meds, Type I DM or HbA1C >9%, GFR<40 ml/min, any history of CV event (CVA, TIA, MI, CABG, CHF NYHA III-IV), AICD or CRT-D, night shift workers

Principal Investigator: John Schindler, MD

Sub-Investigators: Evan Ray, MD and Matthew Muldoon, MD

AMPLATZER™ Post-Infarct Muscular VSD Occluder

The AMPLATZER™ Post-Infarct Muscular VSD Occluder (PIVSD) is a Humanitarian Use Device (HUD) which was granted approval for use in the United States under a Humanitarian Device Exemption (HDE) on January 10, 2017. The AMPLATZER™ PIVSD is a percutaneous transcatheter occlusion device intended for closure of post MI muscular VSDs in patients who are not satisfactory surgical candidates.

Principal Investigator: A.J. Conrad Smith, MD

HARP: NYU Women's Heart Attack Research Program (HARP)

Multicenter, diagnostic observational study employing standardized imaging protocols in women with MI with non-obstructive CAD (MINOCA) to determine the prevalence and composition of disrupted plaque and the prevalence and location of myocardial abnormalities. Enrollment is at the time of diagnostic angiography. Questionnaires will be administered to assess psychosocial stress leading up to the event. Eligible patients will undergo 3-vessel optical coherence tomography (OCT) at the time of angio and Cardiac MR imaging within one week. Findings of OCT and CMR will be integrated to identify vascular causes (plaque disruption, dissection and coronary artery spasm), to assess plaque composition, edema and to synthesize the findings of OCT and CMR to identify the underlying etiology of MINOCA in women.

Inclusion criteria: Women age \geq 21 years, acute ischemic symptoms with objective evidence of MI (elevated troponin or ST elevation \geq 1mm)

Principal Investigator: Catalin Toma, MD

Progress CTO Registry

Multicenter Registry of Chronic Total Occlusion Interventions; This chart review data collection registry can have a significant impact on the care of patients with coronary CTOs by allowing better understanding and improvement of the techniques and outcomes of CTO PCI.

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 patients with CAD.

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

Principal Investigator: Prem Soman, MD, PhD

ALIVE: Clinical Study of the BioVentric 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

MINT (Myocardial Infarction and Transfusion)

Randomized, unblinded, multicenter clinical trial randomly allocates 3,500 patients with acute myocardial infarction and a hemoglobin concentration less than 10 g/dL to be treated either according to a liberal or restrictive blood transfusion strategy; purpose of the trial is to assess RBC transfusion strategies currently used in clinical practice and important medical events. RBCs are a limited and expensive medical therapy. Physicians frequently transfuse patients to maintain specific (and often differing) hemoglobin levels, despite the lack of evidence supporting the strategy. The study results, which will determine the benefit (or risk) of a liberal transfusion strategy, will influence the allocation of red blood cells worldwide.

Inclusion criteria: Age ≥ 18 years, presumptive diagnosis of STEMI or NSTEMI (Type I and II), HgB <10g/dL

Principal Investigator: Catalin Toma, MD

Sub-Investigator: Mark Schmidhofer, MD

BRICK (Biochemical and Renoprotective Effects of Remote Ischemic Preconditioning on Contrast-induced Kidney Disease)

Double-blind, sham-controlled, RCT examining the effect of remote ischemic pre-conditioning (RIPC) on incidence of CI-AKI following cardiac cath and PCI in high risk patients with CAD. Patients will be randomized to RIPC or sham-RIPC, receiving the intervention prior to cardiac catheterization; RIPC involves 5 minute cycles of non-injurious ischemia using a manual BP cuff placed around the upper arm inflated to 200 mmHg for RIPC group, 10mmHg for Sham-RIPC group and interrupted three times for 5-minutes of reperfusion with the cuff deflated (total of 30 minutes).

Inclusion Criteria: Age ≥ 18 years with diagnosis of unstable angina or NSTEMI, planned for cardiac catheterization and at high risk for CI-AKI, determined by Mehran's CI-AKI risk score of ≥ 11

Principal Investigator: Oladipupo Olafiranye, MD

Precise Rx (Pharmacogenomics-guided Care to Improve the Safety and Effectiveness of Medications)

A study to measure the performance and impact of pharmacogenomics-guided drug therapy individualization following PCI. We hypothesize that: targeted genetic variants are detectable in UPMC patients, point-of-care interventions can be accomplished, clinical outcomes are improved, and patients find these processes acceptable. PreCISE-Rx establishes to create a bio-bank to enable future research use of pharmacogenomic research.

Inclusion criteria: Patients (>18 years of age) who have received or are planned for PCI and pharmacogenomic testing at UPMC

Principal Investigator: Philip Empey, PharmD, PhD

Attribute-CM

A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of AG10 in Subjects with Symptomatic Transthyretin Amyloid Cardiomyopathy. The primary endpoint is to evaluate the change in distance walked during the 6MWT from baseline to Month 12 of treatment and to determine a hierarchical combination of All-Cause mortality and CV-related hospitalization over a 30-month period.

Inclusion Criteria: ages 18-90; diagnosis of ATTR-CM (wild-type TTR or variant TTR); history of HF or clinical evidence of HF; NYHA Class I-III due to ATTR-CM; (if applicable) must be on stable CV GDMT for at least two weeks; completed ≥ 150 m on the 6MWT for two consecutive tests; NT-pro BNP levels ≥ 300 pg/mL; LV wall thickness ≥ 13 mm; WOCBP agree to use acceptable methods of contraception.

Exclusion Criteria: Acute MI, ACS, or coronary revascularization within 90 days; experienced stroke within 90 days; hemodynamic instability; likely to undergo OHTx within one year; diagnosis of light-chain amyloidosis; abnormal LFTs >3 x ULN; NT-pro BNP levels ≥ 7000 pg/mL; eGFR <15 mL/min/1.73m²; current treatment for ATTR-CM with Tafamidis or with marketed drug products lacking a labeled indication for ATTR-CM, patisiran, inotersen, green tea extract, or any investigational agent within 14 days or 90 days for patisiran and 180 days for inotersen; requires treatment with calcium channel blockers or digitalis

Principal Investigator: Prem Soman, MD, PhD

Nuc Gene

Study to assess the prevalence and determinants of global myocardial flow reserve abnormalities and its association with a specific gene variant in African-American women with chest pain that are referred for myocardial perfusion imaging.

Inclusion criteria: African-American females referred for clinically indicated pharmacological stress testing for chest pain

Principal Investigator: Prem Soman, MD, PhD

Disrupt CAD

Multicenter, single arm study designed to evaluate the safety and performance of the Shockwave Coronary Rx Lithoplasty® System to treat calcified lesions in the coronary arteries for the purpose of enhancing the placement of stents and reducing the ultimate residual stenosis. Patients will be enrolled and consented in the study based on history and in some instances an angiogram obtained prior to the study. The study is designed to demonstrate that the Shockwave device can safely and effectively deliver localized shockwave energy for balloon dilatation of calcified, stenotic, coronary arteries. Patients will be followed through discharge and at 30 and 180 days. A subset of up to five (5) subjects will receive an angiographic assessment at the 180 day follow up visit, per the Sponsor's discretion.

Inclusion Criteria: Patients w/native CAD including stable or unstable angina and silent ischemia, suitable for PCI; negative troponin within 12 hours prior to procedure; Single, de novo lesion ≤ 32 mm length in an artery w/ $\geq 50\%$ stenosis, TIMI 3 flow and diameter of 2.5 mm - 4.0 mm;

Presence of calcification within the lesion on both sides of the vessel as assessed by angiography

Exclusion Criteria: Concomitant use of Atherectomy, Specialty balloon, or investigational coronary devices; prior PCI within the last 30 days; planned cardiovascular interventions within 30 days post index procedure; second lesion with $\geq 50\%$ stenosis in the same target vessel; LVEF $< 40\%$; serum creatinine >2.5 mg/dL; AMI in past month; CVA or TIA w/in 3 months; previous stent procedure within 5 mm of target lesion

Principal Investigator: Catalin Toma, MD

Sub-Investigators: Conrad Smith, MD; Ashley Lee, MD; John Schindler, MD

MAVA-LTE

A long-term safety extension study of Mavacamten in adults who have completed MAVERICK-HCM (for Non-Obstructive Hypertrophic Cardiomyopathy) or EXPLORER-HCM (Obstructive Hypertrophic Cardiomyopathy).

Inclusion Criteria: Completion of the Parent Study, documented LVEF $\geq 50\%$ by TTE, adequate acoustic windows to enable accurate TTEs.

Exclusion Criteria: QTcF > 500 ms at screening or any other ECG abnormality considered by the investigator to pose a risk to participant safety

Principal Investigator: Timothy Wong, MD

VESALIUS-CV

A double-blind, randomized, placebo-controlled, multicenter study to evaluate the impact of Evolocumab (Repatha®) on major cardiovascular events in patients at high cardiovascular risk without prior myocardial infarction or stroke. The primary objective of this study is to evaluate the effect of treatment with Evolocumab, compared with placebo, on the risk for coronary heart disease death, myocardial infarction (MI), or ischemic stroke, whichever occurs first, in subjects at high cardiovascular risk without prior MI or stroke and receiving optimized lipid-lowering therapy.

Inclusion Criteria: Subjects must be ≥ 50 years (men) or ≥ 55 years (women) to < 80 years of age (either sex) and have an LDL-C ≥ 100 mg/dL (≥ 2.6 mmol/L) or non-high density lipoprotein (HDL)-C ≥ 130 mg/dL (≥ 3.4 mmol/L) at screening, after ≥ 4 weeks of optimized lipid-lowering therapy; Diagnostic evidence of at least 1 of the following (A - D) at screening: A. Significant CAD, B. Significant atherosclerotic cerebrovascular disease, C. Significant peripheral artery disease, D. Diabetes; and at least one high risk criteria (to be determined by investigator)

Principal Investigator: Aryan Aiyer, MD

Sub-Investigators: Catalin Toma, MD, Timothy Wong, MD

Electrophysiology

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

SMART MSP (Strategic Management to Improve CRT Using Multi-Site Pacing Post Approval Study)

Prospective, multicenter, single arm, post approval study to evaluate the effectiveness of Boston Scientific's Left Ventricular Multisite Pacing feature in the Resonate Family of CRT-D devices and confirm safety when used in accordance with its approved labeling.

Inclusion criteria: Subjects who received de novo implantation of Boston Scientific's Resonate family CRT-D devices with the required features for the study or device upgrade from single or dual chamber pacemaker or ICD. Subjects must have functional RA and RV leads implanted.

Exclusion: Documented history of permanent Atrial Fibrillation or permanent complete AV block are excluded.

Principal Investigator: Sandeep Jain, MD

Symplixity AF: Prospective, randomized, multicenter, investigational clinical study evaluating the feasibility of performing both renal artery denervation and pulmonary vein isolation on the same patient with the intent of characterizing both safety and effectiveness in a paroxysmal and persistent atrial fibrillation (AF) population with hypertension.

Key Inclusion Criteria: Age 18-80, drug refractory recurrent symptomatic paroxysmal or persistent AF, systolic BP > 140 mm Hg.

Key Exclusion Criteria: Active systemic infection, pulmonary vein stents, Type 1 diabetes, NYHA IV, ineligible renal artery anatomy, primary pulmonary hypertension, presence of any pacemaker or ICD; significant PVD, AAA, anemia or thrombocytopenia, previous organ transplant.

Principal Investigator: Samir Saba, MD

JAVA-CRT (Junctional AV Ablation in CRT-D patients with Atrial Fibrillation)

Unblinded, randomized, controlled clinical trial to determine if patients with permanent Atrial Fibrillation who meet conventional criteria for CRT-D and undergo AVJ ablation have improved left ventricular remodeling as assessed by left ventricular end-systolic volume reduction $\geq 15\%$ from baseline to 6 months.

Inclusion Criteria: Age > 21 years, existing indication for de novo CRT device, ischemic or nonischemic cardiomyopathy, LVEF $\leq 35\%$ within 12 months prior to or on consent date, NYHA class II-IV (ambulatory), QRS ≥ 120 ms for LBBB and ≥ 150 ms for non-LBBB patients.

Exclusion Criteria: Ventricular rate > 90 bpm at rest despite maximal medical therapy, ventricular rate < 50 bpm at rest. Heart block/symptomatic bradycardia that necessitates permanent pacing. Severe aortic or mitral valvular heart disease. Prior AVJ ablation. Renal failure requiring dialysis.

Principal Investigator: Sandeep Jain, MD

SOLVE CRT (Stimulation of the Left Ventricular Endocardium for Cardiac Resynchronization Therapy in Non-Responders and Previously Untreatable Patients)

Prospective, two-arm, randomized, double blind, multicenter study to demonstrate the safety and effectiveness of the WiSE CRT System. The WiSE CRT System is indicated for patients considered CRT non-responders or previously untreatable and meeting established CRT treatment criteria. The WiSE CRT System provides endocardial left ventricular stimulation, synchronized to the right ventricular pacing output pulse of a commercially-available implanted pacemaker, ICD, CRT-P, or CRT-D to achieve Cardiac Resynchronization Therapy.

Inclusion: Patients with a class I or IIa indication for implantation of a CRT-D device according to current available guidelines. Non-responders are defined as patients who have a CRT system that is functional and despite optimal device programming the patients have not responded (EF has remained unchanged or worsened and the patient's clinical status has remained unchanged or worsened). Or previously untreatable patients who are a full or partial CRT system, who are deemed as 'previously untreatable' (patients with failed CS lead implantation, CS lead is programmed off, high risk upgrade: relative contraindication to CS lead implant).

Exclusion: Persistent or permanent atrial arrhythmias (or cardioversion for atrial fibrillation) within the past 1-month, pure RBBB, LVEED ≥ 8 cm, chronic hemodialysis, mechanical aortic valves or TAVR valves, persistent or permanent atrial arrhythmias, moderate or severe aortic stenosis.

Principal Investigator: Samir Saba, MD

ECG Belt

ECG Belt for CRT Response is a prospective, interventional, randomized, multi-center, investigational, pre-market research study. The objective is to compare ECG belt managed CRT patients and a 'no ECG belt' CRT group with respect to left ventricular remodeling. ECG belt will be used at implant and/or follow-up to help implanters choose an optimal LV lead position (at implant) within the recommended locations for LV lead implantation and optimize pacing vector/timing parameters (during implant and follow-up) in line with EHRA/HRS expert consensus.

Inclusion Criteria: Indicated for CRT implant and planned to be implanted with a Medtronic CRT device with AdaptivCRT and an Attain Performa quadripolar lead, QRS duration ≥ 120 ms, Meets at least one of the following criteria: QRS duration < 150ms, Lack of complete left bundle branch block on baseline ECG, or Ischemic cardiomyopathy.

Key Exclusion Criteria: Permanent/persistent AF or presenting with AF with ventricular rate ≥ 90 BPM, Pre-existing LV lead or other confounding devices e.g. LVAD, Vagal Nerve Stimulator, Currently implanted with IPG or ICD with > 10% pacing, Complete AV block.

Principal Investigator: Andrew Voigt, MD

PREEMPT-HF

PRECision Event Monitoring of PatientS with Heart Failure using HeartLogic is a global, multi-center, post-market prospective, non-randomized study. The goal of the PREEMPT-HF study is to collect device and clinical event data to evaluate extended applications of the HeartLogic Heart Failure Diagnostic in a broad spectrum of heart failure (HF) patients with an implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D).

Key Inclusion Criteria: Subject has a documented diagnosis of heart failure, Subject has a Boston Scientific CRT-D or ICD device implant that has HeartLogic with Heart Failure Sensors turned ON, Respiratory Sensor turned ON, and Sleep Incline Sensor turned ON, Subject has an active bipolar RV lead implant, Subject is enrolled in LATITUDE (NXT 5.0 or future version), and is willing to be remotely monitored from the baseline visit for approximately 12 months with HeartLogic disabled.

Key Exclusion Criteria: Subject has received or is scheduled to receive a heart transplant or ventricular assist device (VAD), Subject is enrolled in any concurrent clinical study without prior Boston Scientific written approval (excluding registries), Subject has a life expectancy of less than 12 months, Subject has a history of non-compliance to medical care or known inability to comply with requirements of the clinical study protocol.

Principal Investigator: Raveen Bazaz, MD

MARVEN

Clinical, Electrocardiographic, and Cardiac Magnetic Resonance Imaging Risk Factors Associated with Ventricular Tachyarrhythmias in Nonischemic Cardiomyopathy Current guidelines for cardiac resynchronization therapy defibrillator (CRT-D) device implantation indications are based on left ventricular ejection fraction and QRS duration and further risk stratification of arrhythmic events is needed to optimize device therapy in nonischemic cardiomyopathy (NICM) patients. The purpose of the MARVEN study is to determine what clinical, ECG, and cardiac magnetic resonance imaging (CMR) factors identify patients at risk for developing rapid irregular heartbeats requiring therapy by implantable defibrillator. The CRT-D implant procedure is not part of the study. However, information about the procedure and device will be collected for this study along with a 24-hour Holter monitor and CMR imaging prior to the CRT-D implant.

Key Inclusion Criteria: NICM patients, 21 years of age and older, meeting primary prevention indications for CRT-D on optimal pharmacologic therapy for at least 3 calendar months after NICM diagnosis, in sinus rhythm by most recent ECG qualifying patient for CRT-D, willingness to undergo CRT-D implant with remote interrogation enabled within two months after consent, if no CMR within six months of consent date or quality of prior CMR not sufficient, willingness to undergo CMR imaging prior to CRT-D implant.

Key Exclusion Criteria: Atrial fibrillation or flutter, history of MI/PCI/CABG (serum markers or imaging) or evidence of coronary disease with increased likelihood of undergoing PCI or CABG, upgrade to CRT from ICD or pacemaker, secondary prevention indication after documented cardiac arrest, severe claustrophobia, renal insufficiency or known allergy to gadolinium-based contrast.

Principal Investigator: Samir Saba, MD, FACC, FHRS

STELLAR

This clinical study is a prospective, multicenter, single-arm clinical evaluation of the Multi-Electrode Radiofrequency (RF) Balloon catheter. The purpose of this study is to evaluate the overall safety and effectiveness of the Multi-Electrode RF Balloon catheter, in conjunction with the Multi-Electrode Circular Diagnostic catheter and Multi-Channel RF Generator, for the treatment of drug refractory Paroxysmal Atrial Fibrillation (PAF).

Key Inclusion Criteria: Diagnosed with symptomatic atrial fibrillation; Failed at least one Class I or Class III AAD; Age 18-75; Able and willing to comply with all follow up and visit requirements.

Key Exclusion Criteria: Atrial fibrillation secondary to electrolyte imbalance, thyroid disease, or reversible or non-cardiac cause; previous surgical or catheter ablation for AF; previously diagnosed with persistent or long-standing persistent afib and/or continuous afib > 7 days; PCI within past two months; valve repair or replacement; any carotid stenting or endarterectomy within the past 6 months, CABG, cardiac surgery, or valvular cardiac surgical procedure within the past 6 months; documented LA thrombus within 1 day prior to the index procedure; EF <40%; contraindication to anticoagulation or history of bleeding abnormalities; myocardial infarction within the past 2 months; documented stroke within past 12 months; rheumatic heart disease; uncontrolled heart failure; awaiting heart transplant; unstable angina; acute illness/infection; pacemaker or defibrillator; significant pulmonary disease; significant congenital anomaly; women who are pregnant or breastfeeding; known pulmonary vein stenosis; presence of IVC Filter.

Principal Investigator: Andrew Voigt, MD

CRT-P vs CRT-D

Cardiac Resynchronization in the Elderly: Piloting Pacemaker vs. Defibrillator Therapy; Pilot trial that is designed as a randomized, controlled trial for older patients (≥ 75 years) who are indicated for CRT device implantation to receive a CRT-P or CRT-D. Information collected will help to assess the ability to enroll and retain older patients in a randomized controlled trial of CRT-P versus CRT-D in preparation for a large pivotal trial.

Key Inclusion Criteria: Age ≥ 75 years; EF $\geq 35\%$, QRS width >120 ms; NYHA II, III, or ambulatory IV for HF; patient undergoing de novo CRT device implantation or CRT-D device change out for battery depletion

Key Exclusion Criteria: Patient within 40 days of acute myocardial infarction; patient within 3 months of cardiac revascularization; patient with prior history of cardiac arrest or documented sustained ventricular arrhythmia; patients with dementia; participating in any other clinical trials

Principal Investigator: Samir Saba, MD, FACC, FHRS

SYMPPLICITY AF

A prospective, randomized, multi-center clinical study to evaluate the feasibility of performing both renal artery denervation and pulmonary vein isolation on the same patient with the intent of characterizing both safety and effectiveness in a paroxysmal and persistent atrial fibrillation (AF) population with hypertension.

Inclusion Criteria: Drug refractory recurrent symptomatic paroxysmal or persistent atrial fibrillation; Office-based systolic blood pressure > 140 mm Hg; Age 18 years to 80 years old; Willing to give informed consent and agree to all study procedures, Willing and able to be remotely monitored through the Medtronic CareLink[®] Network via LINQ implant

Key Exclusion Criteria: Active systemic infection; cryoglobulinemia; One or more pulmonary vein stents; Type I Diabetes; NYHA Class IV heart failure within the past 6 months; Renal artery anatomy that is ineligible for treatment; GFR <30 ; primary pulmonary hypertension; pheochromocytoma, Cushing's Disease, coarctation of the aorta, untreated hyperthyroidism, primary hyperparathyroidism or hyperaldosteronism; Myocardial infarction, unstable angina pectoris, syncope, PCI/PTCA, or coronary artery stenting within 3 months prior to signing the consent form; Cerebrovascular accident within 1 month; Prior ablation for afib in the left atrium; Presence of a pacemaker, atrial defibrillator or any implantable cardiac defibrillator; Cardiac valve stenosis; Anything interfere with ability to obtain an accurate blood pressure measurement using automatic blood pressure monitor; Serious medical condition, which may adversely affect the safety and/or effectiveness of the participant or the trial; Pregnant, nursing or planning to be pregnant; Known history of drug use or alcohol dependency, lacks the ability to comprehend or follow instructions, or would be unlikely or unable to comply with study follow-up requirements; Previous organ transplant; Currently enrolled or plans to participate in a potentially confounding drug or device trial during the course of this study

Principal Investigator: Samir Saba, MD, FACC, FHRS