Active Research Studies at Corewell Health West

2/9/2024

Cardiovascular Health Cardiothoracic Surgery	
LeAPPS	Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction Trial To demonstrate the effectiveness of LAA exclusion (LAAE) for the prevention of ischemic stroke or systemic arterial embolism in subjects undergoing cardiac surgery who have risk factors for atrial fibrillation and ischemic stroke.
A2CPS	Acute to Chronic Pain Signatures Program
Terminate AF	To demonstrate the safety and effectiveness of the Cardioblate Surgical Ablation iRF and Cryoflex hand held devices for the treatment of non-paroxysmal atrial fibrillation in patients requiring concomitant cardiac surgery.
Electrophysiology	
AVANT GUARD	Pulsed field ablation as first-line ablation treatment for persistent Afib versus initial treatment with anti-arrhythmic drugs
REACT-AF	IRB submitted reliance agreement documents to JHU on 2/10
Heart Failure	
nHCM Study - ODYSSEY	A Randomized, Double-blind, Placebo-controlled Clinical Study to Evaluate Mavacamten in Adults with Symptomatic Nonobstructive Hypertrophic Cardiomyopathy
Electrocardiogram-based Artificial Intelligence-assisted Detection (ECG-AID) of Heart Disease	A retrospective and prospective study. Electrocardiogram-based Artificial Intelligence-assisted Detection of heart disease (ECG-AID) is an implementation study to gather real-world preliminary evidence on the utility of Tempus AirTM when integrated into a clinical system. The study will involve two phases: 1) A retrospective phase where the devices can be validated within a limited set of patients from each site and 2) a prospective phase where the diagnostic yield and clinical utility of the devices can be directly measured.
Heart Transplant	

ProTECT Heart Registry	The primary objective of the study is to assess the clinical utility of combining Prospera testing with routine transplant management in detecting rejection or heart allograft dysfunction.
Interventional	
CERROS Pilot Study	Prospective pilot study enrolling 20 subjects. Objective is to determine whether a reduced radiation protocol in which angiograms are acquired at ultralow radiation doses and then processed using spatiotemporal enhancement software can produce similar qu
HEAL-LAA	Newest generation of Watchman
CERAMICS	Can Escalation Reduce Acute Myocardial Infartion Mortality in Cardiogenic Shock. Registry to capture MI patients in CGS.
Discover HCM	Using Real World Evidence (FDA reporting) To estimate the incidence rate of new or worsening heart failure (HF) due to systolic dysfunction (defined as symptomatic left ventricular ejection fraction [LVEF] < 50%) among patients with symptomatic obstructive HCM during periods of exposure to mavacamten and non-mavacamten therapy
SPYRAL AFFIRM	Renal denervation procedure to treat uncontrolled hypertension.
CONFORM Trial	Evaluating the safety and effectiveness of the CLAAS Device by demonstrating non-inferiority to currently marketed LAAO systems in subjects with non-valvular atrial fibrillation, demonstrating the safety of a post procedure pharmacologic antiplatelet regimen that consists of DAPT alone without concomitant anticoagulation therapy (OAC or DOAC), and demonstrating the ability to safely deliver the CLAAS Device using a conscious sedation protocol without general anesthesia.
Impella ECP	To demonstrate Impella ECP has an acceptable rate of Major Adverse Cardiovascular and Cerebrovascular Events (MACCE)
Angiotensin II	in the treatment of vasoplegia in cardiogenic shock patients supported with temporary mechanical circulatory support: A single center experience

PROTECT IV (four)	Prospective, multicenter, randomized, parallel-controlled, open-label two arm Trial with an adaptive design. Eligible subjects will be randomized in a 1:1 ratio to PCI with Impella CP® (Intervention Group) versus standard of care PCI with or without IABP (Control Group).
STEMI-DTU	To demonstrate the safety and effectiveness of primary Left Ventricular unloading and a thirty- minutes delay to reperfusion vs. current standard of care in reducing infarct size and heart failure- related clinical events in patients presenting with anterior ST-Elevation Myocardial Infarction
Nursing Administration	
Heart Up!	A Randomized Controlled Trial to Reduce Hopelessness Through Enhanced Physical Activity in Patients with Ischemic Heart Disease.
Structural Heart	
Evolut Expand TAVR II Pivotal Trial	Obtain safety and effectiveness data to support indication expansion for the Medtronic TAVR System to include patients with moderate, symptomatic AS
Amplatzer PIVSD Study	Amplatzer™ PIVSD Occluder Humanitarian Device Exemption Post-Approval Study. The objective of this retrospective study is to evaluate the safety and probable benefit of the PIVSD Occluder in patients undergoing implantation of the PIVSD Occluder following acute myocardial infarction.
CorCinch Study	Randomized Clinical Evaluation of the AccuCinch® Ventricular Restoration System in Patients who Present with Symptomatic Heart Failure with Reduced Ejection Fraction (HFrEF)
CATALYST Trial	Prospective, randomized, controlled, unblinded, multicenter clinical trial Prospective, randomized, controlled, unblinded, multicenter clinical trial of the Amplatzer™ Amulet™ device in patients with non-valvular atrial fibrillation who are at increased risk for cardioembolic events.
APOLLO Trial	Evaluate the safety and efficacy of Medtronic Intrepid™ TMVR System in patients who are candidates for conventional mitral valve surgery. One arm-TMVR with Intrepid Valve
Vascular	
ROADSTER 3	Post-Approval Study of Transcarotid Artery Revascularization in Standard Risk Patients with Significant Carotid Artery Disease

The objective of this human subjects study is to perform a yearly abdominal CT examination of patients with a recently diagnosed small abdominal aortic aneurysm (AAA) and acquire basic medical history data at each yearly follow up. The scientific goal of this research is to provide a proof-of-concept strategy for implementing a nonlinear membrane based analysis for AAA rupture risk assessment.