Coronary Artery Disease/Myocardial Infarction

SHORTCUT: Shockwave Lithoplasty Compared to Cutting Balloon Treatment in Calcified Coronary Disease – A Randomized Controlled Trial (Short-Cut)
Study Overview: To compare efficacy and safety of CB and IVL alone and after rotational atherectomy for the treatment of calcified coronary lesions
PI: Dr. Michael Ragosta
NCT link: Here (NCT06089135)
IRB# HSR231582
Primary CRC: Annika King

AGENT-IDE: A Prospective, Randomized (2:1), Multicenter Trial to Assess the Safety and Effectiveness of the AgentTM Paclitaxel Coated PTCA Balloon Catheter for the Treatment of Subjects with In-Stent Restenosis (ISR) – LONG LESION Cohort
Study Overview: To assess the safety and effectiveness of the AgentTM Paclitaxel Coated PTCA Balloon Catheter compared to balloon angioplasty (POBA) in patients with in-stent restenosis (ISR) of a previously treated lesion of up to 36 mm in length (by visual estimate) in a native coronary artery 2.0 mm to 4.0 mm in diameter.
PI: Dr. Angela Taylor
NCT link: Here (NCT06492174)
IRB# HSR210256
Primary CRC: Annika King

COMPLETE-2 TRIAL: A randomized trial of physiology-guided versus angiography-guided nonculprit lesion (NCL) complete revascularization strategies and a large-scale observational study of Optical Coherence Tomography in patients with acute myocardial infarction and multivessel coronary artery disease
Study Overview: To determine whether a strategy of physiology-guided complete revascularization is non-inferior to a strategy of angiography-guided complete revascularization on the efficacy composite outcome of cardiovascular (CV) death, new myocardial infarction (MI) or ischemia-driven revascularization (IDR). If non-inferiority is established, superiority of the physiology-guided strategy will be tested & To determine whether a physiology-guided complete revascularization strategy is superior to an angiography-guided complete revascularization strategy in reducing the safety composite outcome of clinically significant bleeding, stroke, stent thrombosis or contrast-associated acute kidney injury.
PI: Dr. Michael Ragosta
NCT link: Here (NCT05701358)
IRB# HSR230353
Primary CRC: Annika King

iSCAD: The International Spontaneous Coronary Artery Dissection Registry
Study Overview: The aim of "iSCAD," the International Spontaneous Coronary Artery Dissection (SCAD) Registry, is to serve as an internationally collaborative, multicenter registry coordinated by an experienced and centralized coordinating center in an effort to increase the pace of participant recruitment, and thereby increase statistical power of studies related to SCAD.
PI: Dr. Patricia Rodriguez-Lozano
NCT link: Study Details | International Spontaneous Coronary Artery Dissection (SCAD) "iSCAD" Registry | ClinicalTrials.gov
IRB# 21876
Primary CRC: Morgan Hamilton

SMILE: Effect of Dapagliflozin on Microvascular function in Women with Symptoms of Coronary Artery Disease
Study Overview: The goal of this clinical trial is to test the effects of a drug (in the drug class called sodium-glucose cotransporter 2 inhibitors) in women who have symptoms of ischemic heart disease. Participants will be randomly assigned to a 12-week course of the study drug, dapagliflozin 10mg, or placebo. Blood flow in the heart will be assessed using stress cardiac magnetic resonance imaging at baseline and 12 weeks. The researchers will compare the results from the two groups.
PI: Dr. Patricia Rodriguez
IRB#: HSR220123
NCT Link: Study Details | Effect of Dapagliflozin on Microvascular Function in Women With Symptoms of Coronary Artery Disease | ClinicalTrials.gov

Primary CRC: Lauren Preston

STRONG: Study Targeting Myocardial Perfusion and Symptom Relief in Women with SGT2 Inhibitors
Study Overview: The study team hypothesizes that Sodium-glucose cotransporter 2 inhibitors treatment will improve Coronary Microvascular Disease in women with anginal symptoms associated with non-obstructive coronary disease by several pathways, including reducing markers of systemic Inflammation and improving coronary blood flow, leading to a reduction of the functional impact of this disease process.
PI: Dr. Patricia Rodriguez
IRB#: 301805
NCT Link: Study Details | Study Targeting Myocardial Perfusion and Symptom Relief in Women with SGLT2 Inhibitors (STRONG) | ClinicalTrials.gov
Primary CRC: Lauren Preston

Colchicine in decompensated HFreF: Myocarditis Therapy with Steroids. Single blind randomized controlled trial to assess the safety and efficacy of high dose pulse intravenous corticosteroid therapy to treat patients with complicated/fulminant acute myocarditis
Study Overview: We hypothesize that treatment with colchicine is safe to start in patients with acutely decompensated HF, and it will significantly inhibit systemic inflammation, as shown by a reduction of biomarkers of systemic inflammation, i.e. hsCRP, in patients with acutely decompensated HF with reduced left ventricular ejection fraction.
PI: Dr. Antonio Abbate
NCT link: Study Details | Colchicine in Acutely Decompensated HFREF | ClinicalTrials.gov
IRB# HSR220446
Primary CRC: Francesco Moroni, MD; Kelly Parker, RN

SOS AMI: Multi-center, double-blind, randomized, placebo-controlled, parallel-group study to evaluate the efficacy and safety of self-administered subcutaneous selatogrel for prevention of all-cause death and treatment of acute myocardial infarction in subjects with a recent history of acute myocardial infarction
Study Overview: The primary objective of the study is to assess the clinical efficacy of selatogrel when self-administered upon occurrence of symptoms suggestive of an acute myocardial infarction (AMI) in subjects at risk of having a recurrent AMI.
PI: Dr. Kanwar Singh
NCT link: Study Details | Selatogrel Outcome Study in Suspected Acute Myocardial Infarction | ClinicalTrials.gov
IRB# HSR 210235
Primary CRC: Kelly Parker, RN

ARTEMIS: Effects of ziltivekimab versus placebo on cardiovascular outcomes in patients with acute myocardial infarction
Study Overview: The aim of the current study is to demonstrate the efficacy and safety of ziltivekimab in reducing the risk of major adverse cardiovascular events when initiated as early as possible in adult patients with ST-elevation and non-ST-elevation myocardial infarction
PI: Dr. Antonio Abbate
NCT link: Study Details | ARTEMIS - A Research Study to Look at How Ziltivekimab Works Compared to Placebo in People With a Heart Attack | ClinicalTrials.gov
IRB# HSR 231612
Primary CRC: Kelly Parker, RN; Morgan Hamilton

Virginia Art4: Phase II clinical trial of Anakinra or Placebo for the treatment of ST-segment elevation myocardial infarction (STEMI)
Study Overview: To determine the effects of Interleukin-1 blockade with anakinra on cardiac reserve and cardiorespiratory fitness in patients with STEMI
PI: Dr. Antonio Abbate
NCT link: Study Details | Interleukin-1 Blockade in Acute Myocardial Infarction to Prevent Heart Failure | ClinicalTrials.gov
IRB# HSR220072
Primary CRC: Kelly Parker, RN

Electrophysiology

PSR: Product Surveillance Registry
Study Overview: To provide continuing evaluation and periodic reporting of the safety and effectiveness of market-released Medtronic products for their intended use.
PI: Dr. Pamela Mason
NCT01524276
NCT link: https://clinicaltrials.gov/study/NCT01524276?term=Product%20surveillance%20registry,%20medtronic&rank=1
IRB-HSR# 18965
Primary CRC: Cathy Roy

RESOLVE AF: A prospective, single arm, multi-center, clinical evaluation of the Ablacath™ Mapping Catheter and Ablamap® System utilizing Electrographic Flow (EGF) mapping to resolve extra-pulmonary vein sources of Atrial Fibrillation and guide ablation therapy.
Study Overview: Demonstrate the safety and effectiveness of the Ablacath™ Mapping Catheter and Ablamap® System in patients with all types of atrial fibrillation (AF) including paroxysmal or persistent or long-standing persistent, undergoing and De Novo or Redo procedures.
PI: Dr. J. Michael Mangrum
NCT05883631
NCT
link: https://clinicaltrials.gov/study/NCT05883631?term=Ablacath%E2%84%A2%20Mapping%20Catheter%20and%20Ablamap%C2%AE%20System%20utilizing%20Electrographic%20Flow%20(EGF)&rank=1
IRB-HSR# 230287
Primary CRC: Cathy Roy

LA Fibrosis: Precision MRI of Left Atrial Fibrosis for Patients with Atrial Fibrillation
Study Overview: Develop and validate a new magnetic resonance imaging (MRI) approach for measuring the severity of fibrosis in the left side of a heart chamber called atrium, for the purpose of predicting whether patients will revert to atrial fibrillation (AF) following initial successful intervention.
PI: Dr. Daniel Kim, Northwestern University; Dr. Kenneth Bilchick, University of Virginia
Unable to locate a NCT number or link
IRB-HSR# 230168
Primary CRC: Cathy Roy

CardioFocus Post-Approval Study of the HEARTLIGHT® Endoscopic Ablation System for the Treatment of Atrial Fibrillation
Study Overview: This is a post-approval study to evaluate the clinical outcomes in a cohort of participants treated during commercial use of the HeartLight System to confirm results of the previously conducted pivotal clinical study.
PI: Dr. J. Michael Mangrum
NCT03168659
NCT link: https://clinicaltrials.gov/study/NCT03168659?lat=42.05645939999999&lng=-87.67526699999999&locStr=Northwestern%20University,%20Clark%20Street,%20Evanston,%20IL&distance=50&cond=Atrial%20Fibrillation&page=5&rank=41
IRB-HSR# 19864
Primary CRC: Cathy Roy

Left vs Left Randomized Clinical Trial
Study Overview: In this prospective, randomized, multi-center clinical trial, the investigators aim to prospectively evaluate the comparative effectiveness His or Left bundle branch pacing (His/LBBP) vs. biventricular pacing (BiVP) in patients with heart failure due to left ventricular systolic dysfunction (LVEF≤50%) and with either a wide QRS (≥130 ms) or with/anticipated >40% pacing
PI: Dr. Rohit Malhotra
NCT05650658
NCT Link: Study Details | Left vs Left Randomized Clinical Trial | ClinicalTrials.gov

IRB-HSR# 230134
Primary CRC: Josh Egan

LEADR LBBAP

Study Overview: The LEADR LBBAP study is being conducted under the existing US FDA Investigational Device Exemption (IDE) for the Next Generation ICD Lead and is designed to confirm the safety and defibrillation efficacy of the Next Generation ICD Lead when placed in the LBBAP location in ICD and LOT-CRT patient population.
PI: Dr. Pamela Mason
NCT04863664
NCT Link: Study Details | Lead EvaluAtion for Defibrillation and Reliability (LEADR) / Lead Evaluation for Defibrillation and Reliability in Left Bundle Branch Area Pacing (LEADR LBBAP) | ClinicalTrials.gov
IRB-HSR# 231548
Primary CRC: Josh Egan

CMR for Cardiac Function in Atrial Fibrillation

Study Overview: The purpose of this study is to determine how atrial fibrillation is affecting patients heart function and the likely impact of returning to sinus rhythm on cardiac function, exercise capacity, and symptoms.
PI: Dr. Kenneth Bilchick
Unable to locate a NCT number or link
IRB-HSR# 220231
Primary CRC: Josh Egan

REACT-AF

Study Overview: REACT-AF is a multicenter prospective, randomized, open-label, blinded endpoint (PROBE design), controlled trial comparing the current Standard Of Care (SOC) of continuous Direct Oral Anticoagulation (DOAC) use versus time-delimited (1 month) DOAC guided by an AF-sensing Smart Watch (AFSW) in participants with a history of paroxysmal or persistent Atrial Fibrillation (AF) and low-to-moderate stroke risk.
PI: Dr. Rohit Malhotra
NCT05836987
NCT Link: Study Details | The Rhythm Evaluation for AntiCoagulaTion With Continuous Monitoring of Atrial Fibrillation | ClinicalTrials.gov
IRB-HSR# 230157
Primary CRC: Josh Egan

Heart Failure

DRIAN-HF: DiuRetics Alone vs. AortIx ENdovascular Device for Acute Heart Failure
Study Overview: To evaluate the safety and effectiveness of the Aortix System versus standard of care medical therapy in patients hospitalized with ADHF and persistent congestion despite usual medical management and who are not being considered for near-term advanced HF therapy
PI: Dr. Steven Philips
NCT link: Here (NCT05677100)
IRB# HSR230436
Primary CRC: Annika King

PHAR Registry: Pulmonary Hypertension Association Registry
Study Overview: Goals: 1) measuring and improving quality of care (including assessing differences in adherence to evidence-based guidelines and establishing benchmarks for health outcomes), 2) determining the clinical effectiveness, comparative effectiveness, and cost effectiveness of treatment approaches, 3) understanding risk factors for outcomes and regional/center differences, and 4) facilitating funded clinical trials of new therapies and collaboration with the PAH community at large, including providers, patients, and their caregivers
PI: Dr. Andrew Mihalek
NCT link: Here (NCT04071327)
IRB# HSR20925
Primary CRC: Annika King

Clonal Hematopoiesis: Assessment of clonal hematopoiesis in subjects with heart failure with preserved ejection fraction (HFpEF) and suspicion of cardiac amyloidosis
Study Overview: To determine whether clonal hematopoiesis is a determinant in the development of cardiac amyloidosis
PI: Dr. Mohammad Abuannadi
NCT link: None.
IRB# HSR230354
Primary CRC: Annika King

Effect of Mavacamten Treatment on Coronary Flow Reserve in oHCM (Mava-PET)
Study Overview: The goal of this observational study is to measure the effect of mavacamten treatment on blood flow in the heart muscle (myocardium) in patients with obstructive hypertrophic cardiomyopathy.
PI: Dr. Michael P. Ayers NCT link: https://clinicaltrials.gov/study/NCT06023186
IRB# HSR 220293
Primary CRC: Caroline Flournoy

Phase 3 Trial to Evaluate the Efficacy and Safety of Aficamten Compared to Placebo in Adults With Symptomatic nHCM (ACACIA-HCM)
Study Overview: This clinical trial will study the effects of aficamten (versus placebo) on the quality of life, exercise capacity, and clinical outcomes of patients with non-obstructive hypertrophic cardiomyopathy.
PI: Dr. Michael P. Ayers NCT link: https://clinicaltrials.gov/study/NCT06081894
IRB# HSR 230535
Primary CRC: Caroline Flournoy

A Study to Evaluate the Efficacy and Safety of Sotagliflozin in Symptomatic Obstructive and Non-obstructive Hypertrophic Cardiomyopathy (SONATA-HCM)
Study Overview: The main purpose of the study is to determine the changes in symptoms and functional limitations in participants with symptomatic hypertrophic cardiomyopathy (HCM) treated with sotagliflozin as compared to placebo.
PI: Dr. Michael P. Ayers NCT link: https://clinicaltrials.gov/study/NCT06481891
IRB# HSR 301549
Primary CRC: Caroline Flournoy

Drain HF: **Diuretics Alone vs. Aortix Endovascular Device for Acute Heart Failure**
Study Overview: Aortix is a circulatory support device for chronic heart failure patients on medical management who have been hospitalized for acute decompensated heart failure (ADHF) and have persistent congestion despite usual medical therapy.
PI: Dr. Steven Philips
NCT link: Study Details | Diuretics Alone vs. Aortix Endovascular Device for Acute Heart Failure | ClinicalTrials.gov
IRB# HSR230436
Primary CRC: Melanie Dean

Ancora-CorCinch 5019 Clinical Evaluation of the AccuCinch Ventricular Restoration System in Patients Who Present With Symptomatic Heart Failure with Reduced Ejection Fraction (HFrEF)
Study Overview: Prospective, randomized, open-label, international, multi-center clinical study to evaluate the safety and efficacy of the AccuCinch Ventricular Restoration System in Patients with heart failure and reduced ejection fraction (HFrEF).
PI: Dr. Mohammed Abuannadi
NCT link: Study Details | Clinical Evaluation of the AccuCinch® Ventricular Restoration System in Patients Who Present With Symptomatic Heart Failure With Reduced Ejection Fraction (HFrEF): The CORCINCH-HF Study | ClinicalTrials.gov
IRB# HSR210065
Primary CRC: Melanie Dean

Responder: Re-evaluation of the Corvia Atrial Shunt Device in a Precision Medicine Trial to Determine Efficacy in Mildly Reduced or Preseved Ejection Fraction (EF) Heart Failure
Study Overview: Multicenter, prospective, randomized, sham controlled, double blinded clinical trial with 1:1 randomization to either a treatment arm with ICE or TEE guided trans-septal puncture and Corvia Atrial Shunt implant vs. ICE or TEE for examination of the atrial septum.
PI: Dr. Mohammed Abuannadi
NCT link: Study Details | RESPONDER-HF Trial | ClinicalTrials.gov
IRB# HSR220440
Primary CRC: Melanie Dean

CERAMICS Study: Can Escalation Reduce Acute Myocardial Infarction Mortality in Cardiogenic Shock
Study Overview: The CERAMICS study is designed to more clearly delineate the current care of acute myocardial infarction with cardiogenic shock (AMICS) patients who are treated with mechanical circulatory support (MCS) devices in the United States with significant experience in MCS, all of whom have the capability of MCS escalation on-site.
PI: Dr. Angela Taylor
NCT link: Study Details | Can Escalation Reduce Acute Myocardial Infarction Mortality in Cardiogenic Shock | ClinicalTrials.gov
IRB# HSR 220361
Primary CRC: Morgan Hamilton

IC14: Phase 1b Pilot Study to Evaluate Atibuclimab (IC14) for Treatment of Acute Decompensated Heart Failure
Study Overview: This pilot study will evaluate the safety, preliminary efficacy, and pharmacokinetics/pharmacodynamics of IC14 in patients with ADHF undergoing standard-of-care treatment as recommended by current clinical guidelines.
PI: Dr. Antonio Abbate
NCT link: Study Details | IC14 for Treatment of Acute Decompensated Heart Failure | ClinicalTrials.gov
IRB# HSR 301721
Primary CRC: Kelly Parker, RN

HERMES: A Research Study to Look at How Ziltivekimab Works Compared to Placebo in People With Heart Failure and Inflammation
Study Overview: To demonstrate the superiority of ziltivekimab 15 mg s.c. once-monthly versus placebo, both added to standard of care, in reducing the risk of CV death and HF events in participants with HFmrEF or HFpEF and systemic inflammation.
PI: Dr. Antonio Abbate
NCT link: Study Details | A Research Study to Look at How Ziltivekimab Works Compared to Placebo in People With Heart Failure and Inflammation | ClinicalTrials.gov
IRB# HSR 230126
Primary CRC: Morgan Hamilton

ABC-CVD: Assessment of Brain-heart Connection in Cardiovascular Diseases– the ABC-CVD study

Study Overview: To measure and compare cerebral tissue oximetry, biomarker profile, and cardiac function in and among patients with acute and chronic CVD associated with an abnormal brain-heart connection, patients with acute and chronic CVD with an expected brain-heart connection, and control participants
PI: Dr. Antonio Abbate
IRB# HSR230172
Primary CRC: Austin Hogwood, PhD

MYTHS: Myocarditis Therapy with Steroids. Single blind randomized controlled trial to assess the safety and efficacy of high dose pulse intravenous corticosteroid therapy to treat patients with complicated/fulminant acute myocarditis
Study Overview: The primary objective is to demonstrate a reduction in the rate of the primary composite endpoint on patients treated with pulsed corticosteroid therapy vs. standard therapy and maximal supportive care.
PI: Dr. Antonio Abbate
NCT link: Study Details | MYTHS - MYocarditis THerapy With Steroids | ClinicalTrials.gov
IRB# HSR231541
Primary CRC: Kelly Parker, RN

ATRIUM: AbatacepT foR ImmUne checkpoint inhibitor associated Myocarditis (ATRIUM): A Phase 3, Investigator-Initiated, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Abatacept Compared to Placebo in Hospitalized Participants with Immune Checkpoint Inhibitor Associated Myocarditis
Study Overview: The primary aim is to test whether abatacept, as compared to placebo, is associated with a reduction in major adverse cardiac events (MACE) among participants hospitalized with myocarditis secondary to an immune checkpoint inhibitor (ICI).
PI: Dr. Antonio Abbate
NCT link: Study Details | Abatacept in Immune Checkpoint Inhibitor Myocarditis | ClinicalTrials.gov
IRB# HSR220368
Primary CRC: Kelly Parker, RN; Lauren Preston

Imaging Technology

Rapid Water: Radiolabeled Perfusion to Identify Coronary Artery Disease Using Water To Evaluate Responses of Myocardial FLOW

Study overview: Diagnostic study to determine the sensitivity and specificity of ^{15}O-H_2O (^{15}O-water) PET imagining study to detect coronary artery disease when compared to standard invasive coronary angiogram, fractional flow reserve or coronary CTA.

PI: Dr. Jamie Bourque

NCT05134012

NCT Link: Study Details | RAdiolabeled Perfusion to Identify Coronary Artery Disease Using WAter To Evaluate Responses of Myocardial FLOW (RAPID-WATER-FLOW) | ClinicalTrials.gov

IRB-HSR# 230340

Primary CRC: Linda Bryceland

Peripheral Artery Disease/Pulmonary Vascular Disease

PERT Consortium Registry
Study Overview: It is the mission of the Consortium to increase awareness of treatment options available to patients with pulmonary embolism, to reduce the worldwide incidence of PE, and to further scientific discovery in the realm of PE research.
PI: Dr. Randy Ramcharitar
IRB# 19591
Primary CRC: Morgan Hamilton

North American Registry for Fibromuscular Dysplasia
Study Overview: The North American Registry for Fibromuscular Dysplasia is a global research effort designed to collect clinical data and provide resources for Fibromuscular dysplasia (FMD) patients and healthcare providers. Registries collect information that can be used to study and learn more about a specific condition. This information will help improve the treatment of patients with FMD in the future.
PI: Dr. Randy Ramcharitar
IRB# 15147
Primary CRC: Morgan Hamilton

U**ltrasound Cavitation Therapy for Critical Limb Ischemia**
Study Overview: In this study, we are exploromg how ultrasound exposure of ultrasound microbubble contrast agents, which produces beneficial shear-mediated bioeffects through cavitation (vibration of microbubbles), can be used to treat patients with severe non-healing ulcers secondary to peripheral arterial disease (PAD) and critical limb ischemia (CLI). The primary outcome measure is whether ultrasound exposure to microbubble contrast agents in the inflow artery and at the wound site can accelerate wound healing.
PI: Dr. Jonathan Lindner
NCT link: Study Details | Ultrasound Cavitation Therapy for CLI | ClinicalTrials.gov (NCT05749250)
HSR220344
Primary CRC: Bethany Gholson

Pregnancy and CV Disease

REBIRTH: Impact of Bromocriptine on Clinical Outcomes for Peripartum Cardiomyopathy
Study Overview: The study will enroll 200 women newly diagnosed with peripartum cardiomyopathy within 5 months postpartum in a randomized placebo controlled trial of bromocriptine therapy to evaluate its impact on myocardial recovery and clinical outcomes. Given that bromocriptine prevents breastfeeding, an additional 50 women with peripartum cardiomyopathy excluded from the trial due to a desire to continue breastfeeding but meeting all other entry criteria will be followed in an observational cohort.
PI: Dr. Patricia Rodriguez
IRB#: HSR230280
NCT Link: Study Details | Impact of Bromocriptine on Clinical Outcomes for Peripartum Cardiomyopathy | ClinicalTrials.gov
Primary CRC: Lauren Preston

COPPER: Cardiovascular Outcomes in Pregnancy and Postpartum Period
Study Outcomes: The objective of the database registry is to track specific information related to pre-conception risk factors, hospitalization, mode of delivery, medical management, various procedures and course after discharge for patients who present with either a pre-existing or de novo cardiac diagnosis during pregnancy, intrapartum and postpartum period. This information can then be used for clinical monitoring and quality improvement purposes. The database will improve data integrity, allow for real-time data entry for multiple users and provide a robust data source that will be used for research studies that may be published.
PI: Dr. Patricia Rodriguez
IRB#: HSR230273
Primary CRC: Lauren Preston

Preventive Medicine and Hypertension

SPYRAL AFFIRM: The SPYRAL AFFIRM Global Clinical Study of Renal Denervation with the Symplicity Spyral Renal Denervation System in Subjects with Uncontrolled Hypertension
Study Overview: The purpose of this single-arm interventional study is to evaluate the long-term safety, efficacy, and durability of the Symplicity Spyral system in subjects treated with renal denervation.
PI: Dr. Kanwar Singh
NCT link: Study Details | SPYRAL AFFIRM Global Study of RDN With the Symplicity Spyral RDN System in Subjects With Uncontrolled HTN | ClinicalTrials.gov
IRB# HSR 230198
Primary CRC: Morgan Hamilton

Valvular Heart Disease/Structural

GORE® CARDIOFORM REDUCE PAS: Septal Occluder and Antiplatelet Medical Management for Reduction of Recurrent Stroke in Patients with Patent Foramen Ovale (PFO): the REDUCE Post Approval Study
Study Overview: To assess the safety and effectiveness of GSO device as observed in the REDUCE pivotal IDE study, and to evaluate the quality of operator education and training and transferability of trial experience to a post-market setting
PI: Dr. John Saxon
NCT link: Here (NCT03821129)
IRB# HSR21546
Primary CRC: Annika King

CLASP II TR CAS: Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial
Study Overview: to establish the safety and efficacy of the Edwards PASCAL Transcatheter Repair System in patients with symptomatic severe tricuspid regurgitation who have been determined to be an intermediate or greater estimated risk of mortality with tricuspid valve surgery.
PI: Dr. John Saxon
NCT link: Search for: Tricuspid Valve Regurgitation, Other terms: CLASP II | Card Results | ClinicalTrials.gov
IRB# HSR190061
Primary CRC: Melanie Dean

Trisol System EFS Study
Study Overview: The objective of this early feasibility study is to gain early clinical insight into Trisol system safety and performance to treat patietns with moderate or greater tricuspid regurgitation.
PI: Dr. John Saxon
NCT link: Search for: Tricuspid Valve Regurgitation, Other terms: Trisol | Card Results | ClinicalTrials.gov
IRB# HSR210297
Primary CRC: Melanie Dean

Cardioband: Clinical Study of Edwards Cardioband FIT Valve Repair System
Study Overview: Multi-center, prospective, single-arm, and non-randomized study designed to evalute the safety and performance of the Edwards Cardioband FIT Repair System.
PI: Dr. John Saxon
NCT link: Study Details | Clinical Study of Edwards Cardioband FIT Valve Repair System | ClinicalTrials.gov
IRB# HSR20702
Primary CRC: Melanie Dean

Repair MR: Percutaneous MitraClip Device or Surgical Mitral Valve Repair in Patients with Primary Mitral Regurgitation Who Are Candidates for Surgery
Study Overview: The objective of this randomized controlled trial (RCT) is to compare the clinical outcome of MitraClip device versus surgical repair in patients with severe primary MR who are at moderate surgical risk and whose mitral valve has been determined to be suitable for correction by MV repair surgery by the cardiac surgeon on the local site heart team.
PI: Dr. Kenan Yount
NCT link: Study Details | MitraClip REPAIR MR Study | ClinicalTrials.gov
IRB# HSR200052
Primary CRC: Melanie Dean

Primary: Percutaneous or Surgical Repair in Mitral Prlapse and Regurgitation for >60 Year-olds
Study Overview: This is a prospective, multicenter, open-label, randomized trial comparing mitral valve (MV) transcatheter edge-to-edge (TEER) to surgical repair (1:1 ratio) in patients with primary, degenerative mitral regurgitation (MR).
PI: Dr. Kenan Yount
NCT link: Search for: Mitral Valve Regurgitation, Other terms: PRIMARY | Card Results | ClinicalTrials.gov
IRB# HSR220063

Primary CRC: Melanie Dean

Ascent ASD: **Safety and Efficacy Study of reSept ASD Occluder for Treating Secundum ASD**
Study Overview: Evaluation of the safety and efficacy of the reSept ASD Occluder to treat patients with clinically significant secundum atrial septal defect.
PI: Dr. Michael Hainstock
NCT link: Study Details | Safety and Efficacy Study of reSept ASD Occluder for Treating Secundum ASD | ClinicalTrials.gov
IRB# HSR200440
Primary CRC: Nadia Ventura-Abbas

CLASP IID/IIF: **Edwards PASCAL CLASP IID/IIF Pivotal Clinical Trial (CLASP IID/IIF)**
Study Overview: To establish the safety and effectiveness of the Edwards PASCAL Transcatheter Valve Repair System in patients with degenerative mitral regurgitation (DMR) who have been determined to be at prohibitive risk for mitral valve surgery by the Heart Team, and in patients with functional mitral regurgitation (FMR) on guideline directed medical therapy (GDMT).
ONLY enrolling in FMR group.
PI: Dr. John Saxon
NCT link: Study Details | Edwards PASCAL CLASP IID/IIF Pivotal Clinical Trial | ClinicalTrials.gov
IRB# 21181
Primary CRC: Nadia Ventura-Abbas

Compassion S3: **Evaluation of the SAPIEN 3 Transcatheter Heart Valve in Patients With Pulmonary Valve Dysfunction**
Study Overview: This study will demonstrate the safety and effectiveness of the Edwards Lifesciences SAPIEN 3/SAPIEN 3 Ultra RESILIA Transcatheter Heart Valve (THV) Systems in subjects with a dysfunctional right ventricular outflow tract (RVOT) conduit or previously implanted valve in the pulmonic position with a clinical indication for intervention.
Only enrolling in failed THV group.
PI: Dr. Michael Hainstock
NCT link: Study Details | COMPASSION S3 - Evaluation of the SAPIEN 3 Transcatheter Heart Valve in Patients With Pulmonary Valve Dysfunction | ClinicalTrials.gov
IRB# 18760
Primary CRC: Nadia Ventura-Abbas

PROTEUS: **VenusP-Valve Pivotal Study (PROTEUS STUDY) (PROTEUS)**
Study Overview: A prospective, multi-center, non-randomized interventional study to evaluate the safety and effectiveness of the VenusP-ValveTM System in patients with native right ventricular outflow tract (RVOT) dysfunction.
PI: Dr. Michael Hainstock
NCT link: Study Details | VenusP-Valve Pivotal Study (PROTEUS STUDY) | ClinicalTrials.gov
IRB# HSR230393
Primary CRC: Nadia Ventura-Abbas

Aortic Stenosis and Loss of Y-chromosome
Study Overview: Loss-of-Y chromosome (LOY) is a phenomenon that occurs in males that is known to activated the transforming growth factor pathway that is critical in the development of AS. LOY may explain the male predominance in AS. The intent of this study is to test the hypothesis that LOY is more common in males with AS compared to age-matched males without AS.
PI: Dr. Jonathan Lindner
NCT Link: Study Details | Loss of Y Chromosome in Aortic Stenosis | ClinicalTrials.gov (NCT05295407)
IRB Tracking# 301597
Primary CRC: Bethany Gholson