Southcoast Health

Active Clinical Trials

- **AMPLATZER™ PFO Occluder Post Approval Study**
  Abbott
  Objective: This study is intended to demonstrate the safety and effectiveness of the AMPLATZER™ PFO Occluder in patients with a **patent foramen ovale who have had a cryptogenic stroke.**
  Dr. Adam Saltzman
  Dr. Benjamin Zorach
  No longer enrolling
  NCT # 03309332

- **Assessment of the Watchman Device in Patients Unsuitable for Oral Anticoagulation** (ASAP TOO)
  Boston Scientific
  Objective: The primary objective is to establish the safety and effectiveness of the WATCHMAN™ Left Atrial Appendage Closure (LAAC) Device, including the post-implant medication regimen, for subjects with **non-valvular atrial fibrillation who are deemed not to be eligible for anti-coagulation therapy** to reduce the risk of stroke.
  Dr. Adam Saltzman
  Dr. Ramin Davoudi
  Dr. Nitesh Sood
  No longer enrolling
  NCT# 02928497

- **CHAMPION AF** (CHAMPION)
  Boston Scientific
  Objective: The primary objective of this study is to determine if left atrial appendage closure with the Watchman device is a reasonable alternative to non-vitamin K oral anticoagulants in patients with **non-valvular atrial fibrillation**.
  Dr. Adam Saltzman
  Dr. Ramin Davoudi
  Dr. Nitesh Sood
  No longer enrolling
  NCT # 04394546

- **Post-Approval Study Protocol For Hybrid Convergent Of Epicardial And Endocardial RF Ablation For The Treatment Of Symptomatic Long-standing Persistent AF (CONVERGE POST-APPROVAL STUDY (PAS))**
  AtriCure
  Objective: The primary objective of CONVERGE PAS is to evaluate clinical outcomes (peri-procedural and long-term) in a cohort of patients treated during commercial use of the EPi-Sense® Guided Coagulation System to **treat symptomatic long-standing persistent atrial fibrillation (AF)** patients who are **refractory or intolerant to at least one Class I and/or III AAD**.
  Dr. Nitesh Sood
  Dr. Ramin Davoudi
  Dr. Arnold Giedrimas

Southcoast Health

Dr. Jacob Kriegel
Dr. Peter Lee
Currently enrolling
NCT# 05393180

- **STOP AF PAS**
  Medtronic
  Objective: Demonstrate the superiority of cryoballoon ablation as compared to antiarrhythmic drug (AAD) therapy in terms of the rate of freedom from atrial fibrillation/atrial flutter in a **non-drug refactory paroxysmal atrial fibrillation population.**
  Dr. Nitesh Sood
  Dr. Ramin Davoudi
  Dr. Arnold Giedrimas
  Currently enrolling
  NCT# 027532737

- **A Prospective Randomized Multicenter Global Study Comapring Pulsed Field Ablation versus Anti-Arrhyhthmic Drug Therapy as a First Line Treatment for Persistent Atrial Fibrillation/ AVANT GUARD**
  Boston Scientific
  Objective: The purpose of this study is to establish the safety and effectiveness of pulsed field ablation as a first-line ablation treatment for subjects with **persistent atrial fibrillation** as compared to subjects who received an initial treatment with antiarrhythmic drugs.
  Dr. Nitesh Sood
  Dr. Arnold Giedrimas
  Currently enrolling
  NCT# 06096337

- **VOLT AF-IDE**
  Abbott Medical
  Objective: The objective of the VOLT-AF study is to demonstrate that the Volt™ PFA System (Volt PFA System) is safe and effective for the treatment of **symptomatic, recurrent, drug refractory paroxysmal and persistent atrial fibrillation (AF).**
  Dr. Ramin Davoudi
  Dr. Arnold Giedrimas
  No longer enrolling
  NCT# 06223789

- **IMACOR One Touch Hemodynamics (OTH) Auto Segmentation Algorithm Performance Assessment Non-Significant Risk (NSR) Study**
  IMACOR
  Objective: Via transesophageal echocardiogram, provide direct visualization of cardiac filling and function to assess and guide interventions for **critically ill patients in high acuity settings.**
  Dr. Christopher Abadi
  Currently enrolling
  NCT# 02048566

Southcoast Health

- **JET Enhanced Thrombectomy Intervention** (JETi Registry)
  Walk Vascular
  Objective: A prospective, multi-center observational registry with primary objectives to assess the **percent change in occlusion** from pre-JETi post-JETi **thrombectomy** and to assess outcomes of those affected by rethrombosis of the treated vessels throughout a 12 month follow up.
  Dr. Richard Pin (also National Principal Investigator)
  Dr. Mark Perry
  Dr. Christopher Tanga
  No longer enrolling
  NCT# 04370691

- **Abbott LIFE BTK PK**
  Abbott Medical
  Objective: To test the safety and effectiveness of Abbott's Esprit™ BTK scaffold in patients with **critical limb ischemia**. This trial is running in conjunction with a pharmacokinetic sub study.
  Dr. Richard Pin
  Dr. Mark Perry
  Dr. Christopher Tanga
  No longer enrolling
  NCT# 04227899 (main study)
  NCT# 05208905 (sub study)

- **Protection Against Emboli During Carotid Artery Stenting Using a Neuroguard IEP Direct 3-in-1 Delivery System Comprised of a Post Dilation Balloon, Inegrated Embolic Filter, and a Novel Carotid Stent III/ PERFORMANCE III**
  Contego
  Objective: To evaluate the safety and effectiveness of direct carotid access for stenting using the Neuroguard IEP® Direct System in subjects at elevated risk for adverse events following carotid endarterectomy (CEA) for **carotid artery stenosis.**
  Dr. Richard Pin
  Dr. Mark Perry
  Currently enrolling
  NCT# 05845710

- **Prospective, Multi-center, Single Arm Study of the Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System for the Treatment of Calcified Peripheral Arterial Disease (PAD) in Below-the Knee (BTK) Arteries/ DISRUPT PAD BTK**
  Shockwave Medical
  Objective: The objective of this study is to assess the continued safety and effectiveness of the Shockwave Medical Peripheral IVL System for the **treatment of calcified, stenotic BelowTheKnee arteries.**
  Dr. Richard Pin
  Dr. Mark Perry
  Dr. Christopher Tanga
  No longer enrolling
  NCT# 05007925

- **Forward-shifted Intravascular Lithotripsy (IVL) Technology in a Prospective, Multi-center, single-arm Investigational Device Exemption (IDE) Study/ FORWARD PAD IDE**

Southcoast Health

Shockwave Medical
Objective: To assess the safety and effectiveness of the Shockwave Medical JAVELIN Peripheral IVL System for the **treatment of heavily calcified, stenotic peripheral arteries**.
Dr. Richard Pin
Dr. Mark Perry
Dr. Christopher Tanga
No longer enrolling
NCT# 05858905

- **STRIKE PE: A Prospective, Multicenter Study of the Indigo Aspiration System Seeking to Evaluate the Long-Term Safety and Outcomes of Treating Pulmonary Embolism**
  Penumbra
  Objective: To evaluate real world, long-term functional outcomes, safety and performance of the Indigo Aspiration System for the treatment of **pulmonary embolism**.
  Dr. Richard Pin
  Dr. Mark Perry
  Dr. Christopher Tanga
  Currently enrolling
  NCT# 04798261

- **ESPRIT BTK Post Approval Study**
  Abbott Medical
  Objective: Designed to perform a post-market evaluation of the ESPRIT BTK Everolimus Resorbable Scaffold System for the planned treatment of **narrowed infrapopliteal lesions** in real-world settings.
  Dr. Richard Pin
  Dr. Mark Perry
  Dr. Christopher Tanga
  Currently enrolling
  NCT# 06656364

Persons seeking more information about any of the above trials can search the NCT # on https://www.clinicaltrials.gov/.