

Active Clinical Trials

AMPLATZERTM PFO Occluder Post Approval Study

Abbott

Objective: This study is intended to demonstrate the safety and effectiveness of the AMPLATZERTM 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

• <u>As</u>sessment of the Watchman Device in <u>Patients Unsuitable for Oral Anticoagulation</u> (ASAP TOO)

Boston Scientific

Objective: The primary objective is to establish the safety and effectiveness of the WATCHMANTM 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



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 EspritTM 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/.