Cardiology Research

Approved: **September 2025**
Study: **The MAGICAL-SV – Randomized Clinical Trial: MagicTouch™ Sirolimus-Coated Balloon for Treatment of Coronary Artery Lesions in Small Vessels (CM-US-RO2)**
Investigators: Jonathan Blossom, MD (PI); Cardiology Associates
Summary: The purpose of this study is to compare the efficacy and safety of the MagicTouch™ Sirolimus-Coated Balloon to standard of care drug-eluting stents in small vessel disease.

Approved: **August 2025**
Study: **ERADICATE-AF II – A Trial to Evaluate Renal Artery Denervation in Addition to Catheter Ablation to Eliminate Atrial Fibrillation (00007297)**
Investigators: Karthik Prasad, MD (PI); Cardiology Associates
Summary: The purpose of this study is to determine whether renal denervation performed at the same time using the same catheter insertion site as the cardiac ablation procedure will result in fewer recurrences of atrial fibrillation and improve long term results.

Approved: **May 2025**
Study: **The DAL-302 (dal-GenE-2) trial – A Phase III, Double-blind, Randomized, Placebo-controlled Study to Evaluate the Effects of Dalcetrapib on Cardiovascular Risk in a Genetically Defined Population with a Recent Acute Coronary Syndrome (DAL-302)**
Investigators: William Calhoun, MD (PI); Cardiology Associates
Summary: This study will involve blood sample screening to determine if patients have the AA genotype and will determine the effects of dalcetrapib in those patients who have previously had a cardiac event.

Approved: **February 2025**
Study: **FRACTURE – Modification of Coronary Calcium with Laser Based Intravascular Lithotripsy for Coronary Artery Disease (CR-005614US)**
Investigators: Benjamin Blossom, MD (PI); Cardiology Associates
Summary: The purpose of this study is to demonstrate the safety and efficacy of the Bolt Intravascular Lithotripsy (IVL) System when used to treat coronary artery disease.

Approved:	**March 2025**
Study:	**SPYRAL GEMINI Pilot Study – Global Pilot Study of Renal and Hepatic Combined Denervation in Subjects with Uncontrolled Hypertension with and without High Cardiovascular Risk (MDT23034)**
Investigators:	Barry Bertolet, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to test the safety and efficacy of a procedure called Multi-Organ Denervation using the Gemini System to treat uncontrolled high blood pressure in patients with and without high cardiovascular risk.

Approved:	**November 2024**
Study:	**SIMPLAAFY – WATCHMAN FLX™ Pro Left Atrial Appendage Closure Device with Alternative Post-Implant Monotherapy (97197628)**
Investigators:	James Stone, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to determine the safety and efficacy of medications after the placement of the Watchman FLX™ device.

Approved:	**November 2024**
Study:	**The RAPID-PE Study: Rescue Advanced Protocol without ICU Stay and No Lytic Drip – for the Treatment of Pulmonary Embolism (THRO-CLIN-2024-01)**
Investigators:	Barry Bertolet, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to collect data on the results of treatment with the Bashir Endovascular Catheter and status at seven days and 30 days after treatment.

Approved:	**December 2024**
Study:	**BIO-CONDUCT Study – BIOTRONIK Conduction System Pacing with the Solia Lead – Solia CSP S Cohort (IDE #G210349)**
Investigators:	Karthik Prasad, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to confirm the safety and effectiveness of implanting the Biotronik Solia CSP S lead in the left bundle branch area of the heart.

Approved:	**August 2024**
Study:	**Advancing Cath Lab Results with FFRangio® Coronary Physiology Assessment: The ALL-RISE Study (CWX-08)**
Investigators:	Jonathan Blossom, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to evaluate the clinical safety of FFRangio® guided study treatment compared with standard pressure wire-guided treatment in subjects with coronary artery disease being evaluated for percutaneous coronary intervention.

Approved:	**September 2024**
Study:	**Esprit BTK Post-Approval Study PAS (ABT-CIP-10519)**
Investigators:	Dane Ballard, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to assess the continued safety and effectiveness of the Esprit system. The Esprit system treats narrowed arteries below the knee in patients with critical limb-threatening ischemia.

Approved:	**June 2024**
Study:	**ARTEMIS – Effects of Ziltivekimab versus Placebo on Cardiovascular Outcomes in Patients with Acute Myocardial Infarction**
Investigators:	Barry Bertolet, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to determine if ziltivekimab can be used to treat people who were admitted to the hospital because of a heart attack. Ziltivekimab might reduce the development of heart disease, thereby preventing new heart attacks or strokes.

Approved:	**February 2024**
Study:	**COSIRA-II – Efficacy of the Coronary Sinus Reducer in Patients with Refractory Angina II (022-REDUCLN-002)**
Investigators:	Joseph Adams, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to collect information on the safety and effectiveness of the Reducer device for treatment of patients with refractory angina.

Approved:	**September 2023**
Study:	**MAGICAL ISR – Randomized Clinical Trial - MagicTouch™ Sirolimus-Coated Balloon for Treatment in Coronary Artery Lesions of In-Stent Restenosis (CM-US-RO2)**
Investigators:	Barry Bertolet, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to compare the safety and efficacy of the MagicTouch™ Sirolimus-Coated Balloon in addition to standard balloon angioplasty compared to standard balloon angioplasty alone in subjects with restenosis of a previously placed drug eluting stent.

Approved:	**April 2023**
Study:	**LeAAPS Study – Left Atrial Appendage Exclusion for Prophylactic Stroke Reduction (CP-2021-05)**
Investigators:	David Talton, MD (PI); Vishal Sachdev
Summary:	The purpose of this study is to determine whether use of the AtriClip device will reduce the risk of a stroke.

Approved: **January 2023**
Study: **SPYRAL AFFIRM – Global Clinical Study of Renal Denervation with the Symplicity Spyral Renal Denervation System in Subjects with Uncontrolled Hypertension (MDT20044RDN004)**
Investigators: Barry Bertolet, MD (PI); Cardiology Associates
Summary: The purpose of this study is to collection information on the Symplicity Spyral Renal Denervation system in subjects with varying severity of uncontrolled high blood pressure and associated conditions.

Approved: **March 2023**
Study: **EVOLVE-MI: A Pragmatic Randomized Multicenter Trial of Evolocumab Administered Very Early to Reduce the Risk of Cardiovascular Events in Patients Hospitalized with Acute Myocardial Infarction (20190184)**
Investigators: Barry Bertolet, MD (PI); Cardiology Associates
Summary: The purpose of this study is to determine whether standard of care combined with early treatment of Repatha reduces heart attack, stroke, procedures to improve blood flow, and death, compared to only standard of care.

Approved: **November 2022**
Study: **The CONFORM Pivotal Trial – An Evaluation of the Safety and Effectiveness of the Conformal CLAAS System for Left Atrial Appendage Occlusion (21-101)**
Investigators: Jim Stone, MD (PI); Cardiology Associates
Summary: The purpose of this study is to evaluate the safety and effectiveness of the CLAAS device in sealing off the left atrial appendage for prevention of stroke and stroke related complications associated with atrial fibrillation.

Approved: **November 2022**
Study: **Abbott Atrial Fibrillation Post Approval Study (ABT-CIP-10436)**
Investigators: Karthik Prasad, MD (PI); Cardiology Associates
Summary: The purpose of this post approval study is to gather more information on the safety and effectiveness of the TactiCath™ Ablation Catheter Sensor Enabled™ over a longer period of time.

Approved: **October 2021**
Study: **Disrupt PAD BTK II – Prospective, Multicenter, Single-arm Study of the Shockwave Medical Peripheral Intravascular Lithotripsy (IVL) System for Treatment of Calcified Peripheral Arterial Disease (PAD) in Below-the-Knee (BTK) Arteries (CP 65007)**
Investigators: Barry Bertolet, MD (PI); Cardiology Associates
Summary: The purpose of this study is to further investigate the safety and effectiveness of the Shockwave medical device in the arteries below the knee.

Approved:	**December 2021**
Study:	**ELEGANCE Registry – Drug-Eluting Registry: Real-World Treatment of Lesions in the Peripheral Vasculature (S2444)**
Investigators:	Barry Bertolet, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to collect data on the use of commercially approved drug-eluting devices to understand how these devices are being used in a routine hospital setting to potentially improve patient outcomes and to compare patient outcomes across diverse patient populations.

Approved:	**September 2021**
Study:	**Selatogrel Outcome Study in Suspected Acute Myocardial Infarction (SOS-AMI) Multicenter, 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 (ID-076A301)**
Investigators:	Barry Bertolet, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to determine the efficacy and safety of self administration of selatogrel in subjects having a heart attack.

Approved:	**October 2020**
Study:	**CHAMPION-AF – WATCHMAN FLX versus Non-vitamin K Antagonist Oral Anticoagulation (NOAC) for Embolic Protection in the Management of Patients with Non-valvular Atrial Fibrillation (S2437)**
Investigators:	Jim Stone, MD (PI); Cardiology Associates
Summary:	The purpose of this study is to determine if left atrial appendage closure with the WATCHMAN FLX™ device is a reasonable alternative to oral anticoagulation therapy.