



Vascular Research

Novant Clinical Research Institute

C. Raymond Workman, MD, FACS
Salem Vascular Specialists

NCRI - Snapshot

w Staff- 14

- 7 Clinical Research Coordinators

w 60 active clinical trials

w 18 Investigator/Physicians

w Clinical Focus

- Vascular
- Interventional Cardiology
- Interventional Radiology
- Electrophysiology
- Heart Failure
- ID
- Lipids
- DMII
- HTN
- Stroke

NCRI - Services

w Coordinate clinical trials

- In-Patient, Out-patient
- Drug, Device
- Industry, Federally sponsored, Investigator-Sponsored

w Support clinical research

- Education/Training
- Consultation
 - Budgets, Contracts, Infrastructure building

w Contacts

- Bob Romanchuk, BS, CCRC, CHRC, CIP, Director, NCRI
 - 336.277.0932 rhromanchuk@novanthealth.org
- Wendy Hobbs, BS, CCRC, Manager, NCRI
 - 336.718.5808 wlhobbs@novanthealth.org
- <http://www.forsythmedicalcenter.org/NCRI>



Current Clinical Trials - Vascular

SUPERB Study

- w Comparison of the SUpera[®] PERipheral System in the Superficial Femoral Artery (SUPERB)
- w The primary endpoint will be the primary patency of the SFA evaluated at 12 months
- w Phase III non-randomized
- w Compared against historical controls treated with angioplasty
- w Local PI- Nick Cavros, MD
- w Sponsor: IDev Technologies, Inc.
- w Estimated enrollment goal: 258

CLEVER Trial

- w Claudication: Exercise Versus Endoluminal Revascularization (CLEVER)
- w The purpose of this study is to compare the effectiveness of aortic stent surgery versus exercise therapy in individuals with aortoiliac insufficiency.
- w Local PI: C. Raymond Workman, MD, FACS
- w Sponsor: National Heart, Lung, and Blood Institute (NHLBI)
- w Enrollment Goal: 217

Rheos® Pivotal Trial

- w Rheos™ Baroreflex Hypertension Therapy System
- w Purpose of this clinical trial is to demonstrate the efficacy and safety of the Rheos system in subjects with hypertension that are resistant to treatment with at least three anti-hypertension agents, one of which is a diuretic.
- w Sponsor: CVRx, Inc.
- w Local PI: Stephen J. Motew, MD, FACS
- w Enrollment goal: 300

TriVascular AAA Study

- w Purpose is to determine whether the TriVascular AAA Stent Graft is a safe and effective method of treating abdominal aortic aneurysms
- w Phase II Non-randomized with historical controls
- w Sponsor: TriVascular, Inc.
- w Local PI: Stephen J. Motew, MD, FACS
- w Enrollment Goal: 150

ATTRACT

- w Acute Venous Thrombosis: Thrombus Removal With Adjunctive Catheter-Directed Thrombolysis (ATTRACT)
- w The purpose of this study is to determine if the use of adjunctive Pharmacomechanical Catheter Directed Thrombolysis can prevent the post-thrombotic syndrome(PTS)in patients with symptomatic proximal deep vein thrombosis(DVT)as compared with optimal standard DVT therapy alone.
- w Randomized Phase III trial
- w Sponsor: Washington University School of Medicine
- w Local PI: Stephen J. Motew, MD, FACS
- w Enrollment goal: 693

PEARL II

- w Registry of AngioJet Use in the Peripheral Vascular System (PEARL II)
- w Registry involves the collection of information for research and educational purposes only on the use of AngioJet in the peripheral vascular system.
- w Sponsor: MEDRAD Interventional/Possis
- w Local PI: Stephen J. Motew, MD, FACS
- w Enrollment goal: 500

PEARL

- w A Prospective Observational Registry of Peripheral Use of AngioJet Rheolytic Thrombectomy With Mid-Length Catheters
- w This registry collects observational data about how mid-length AngioJet catheters (ie XPEEDIOR and DVX models) are used in routine clinical practice.
- w Ongoing but no longer enrolling
- w Enrollment goal 500
- w Local PI: Stephen J. Motew MD, FACS
- w

VITALITY

- w Post-Approval Trial of the Talent™ Abdominal Stent Graft to Treat Aortic Aneurysms (VITALITY)
- w Phase IV with historical controls
- w The purpose of this study is to examine the long-term safety and effectiveness of the Talent Abdominal Stent Graft System, in a post-approval environment.
- w On-going but not recruiting
- w Sponsor: Medtronic Endovascular
- w Local PI: C. Raymond Workman, MD, FACS
- w Enrollment goal: 94

CHOICE

- w Carotid Stenting For High Surgical-Risk Patients (CHOICE)
- w The purposes of this study is to 1) Provide additional information about the Abbott Vascular Carotid Stent System 2) Provide post-market surveillance mechanism for documentation of clinical outcomes.
- w Non-randomized Phase IV with historical controls
- w Sponsor: Abbott Vascular
- w Local PI: Don Heck, MD
- w Enrollment goal: 10,000

ACT I

- w Carotid Stenting vs. Surgery of Severe Carotid Artery Disease and Stroke Prevention in Asymptomatic Patients (ACT I)
- w Purpose is to demonstrate the non-inferiority of carotid artery stenting (CAS) using the Emboshield® Embolic Protection System and Emboshield® Pro Embolic Protection System with the Xact® Carotid Stent System to carotid endarterectomy (CEA) for the treatment of asymptomatic extracranial carotid atherosclerotic disease.
- w Sponsor: Abbott Vascular
- w Local PI: Don Heck, MD
- w Enrollment goal: 1658
- w 3:1 enrollment CAS:CEA (stenting: surgery)

CABANA

- w A Carotid Stenting Boston Scientific Surveillance Program (CABANA)
- w CABANA is a multicenter U.S. surveillance registry that will be conducted to compile early clinical outcomes data for the Carotid WALLSTENT Endoprosthesis and FilterWire EZ System in routine clinical practice and to assess the adequacy of the Boston Scientific Corporation (BSC) Carotid Stenting Training Program.
- w Phase IV single group assignment
- w Local PI: Don Heck, MD
- w Enrollment goal: 1100

PICS

- w Penumbra Imaging Collaborative Study (PICS)
- w Phase IV observational study
- w The primary aim of this study is to gather data on the "real world" experience of the Penumbra System
- w The Penumbra System uses a unique microcatheter and Separator™ based thrombus debulking approach to intracranial vessel revascularization.
- w Sponsor: Penumbra Inc.
- w Local PI: Don Heck, MD
- w Enrollment goal: 2000

START

- w Imaging Guided Patient Selection for Interventional Revascularization Therapy (START)
- w Purpose of this clinical evaluation is to determine the safety and effectiveness of the Penumbra System in a stroke cohort who presents within 8 hours from symptom and with a known core infarct volume at admission. The secondary objective is to determine if there is a correlation between infarct volume and functional outcome in treated patients at 90 days post-procedure.
- w Sponsor: Penumbra Inc.
- w Local PI: Don Heck, MD
- w Enrollment goal: 200

CREST

- w Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST)
- w Sponsor: National Institute of Neurological Disorders and Stroke (NINDS)
- w Purpose is to compare stent-assisted carotid angioplasty (CAS) to the traditional and accepted surgical approach of carotid endarterectomy (CEA)
- w On-going but not enrolling
- w Local PI: Don Heck, MD
- w Enrollment goal: 2502

SAMMPRIS

- w Stenting vs. Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS)
- w Sponsor: Medical University of South Carolina
- w Phase III randomized
- w Purpose: Compare intensive medical therapy with intracranial angioplasty and stenting combined with intensive medical therapy in high-risk patients (patients with 70% - 99% intracranial stenosis who had a TIA or stroke within 30 days prior to enrollment) with symptomatic stenosis of a major intracranial artery.
- w Local PI: Don Heck, MD
- w Enrollment goal: 764

SAPPHIRE Worldwide

- w SAPPHIRE Worldwide: Stenting and Angioplasty With Protection in Patients At High-Risk for Endarterectomy
- w The primary objective of this study is to assess the outcomes of stenting with distal protection in the treatment of obstructive carotid artery disease.
- w Sponsor: Cordis Corporation
- w Local PI: Don Heck, MD
- w Enrollment goal: 15,000



Current Clinical Trials - Endocrine

EXAMINE

- w Cardiovascular Outcomes Study of Alogliptin in Subjects With Type 2 Diabetes and Acute Coronary Syndrome (EXAMINE)
- w The purpose of this study is to evaluate the cardiovascular outcomes of alogliptin, once daily (QD), compared with placebo, in addition to standard of care, in subjects with type 2 diabetes mellitus and acute coronary syndrome.
- w Phase III randomized
- w Sponsor: Takeda Global Research & Development Center, Inc.
- w Local PI: Stephen Bissette, M.D.
- w Enrollment goal: 1500



Current Clinical Trials -Infectious Disease

RENSE

- w Study of Daptomycin Safety and Efficacy for Complicated Skin and Skin Structure Infections (cSSSI) and Bacteremia in Renal Impairment (RENSE)
- w Phase IV randomized vs. Vancomycin
- w Sponsor: Cubist Pharmaceuticals
- w Local PI: Stan Link, MD
- w Enrollment goal: 120

GRIFOLS

- w Safety and Efficacy Study of Fibrin Sealant Grifols Evaluated as an Adjunct to Hemostasis
- w The purpose of this study is to evaluate the safety and hemostasis effectiveness of human plasma-derived fibrin sealant Grifols (FS Grifols) in peripheral vascular surgery.
- w Phase II/III randomized
- w Sponsor: Instituto Grifols, S.A.
- w Pending approval in U.S. (International study arm is enrolling)
- w Local PI: C. Raymond Workman, MD, FACS
- w Enrollment goal: 228

QUESTIONS?