2018 Vascular Surgery Clinical Trials

Is your patient a candidate for a clinical trial?

**Referring your patient**
The UPMC Heart and Vascular Institute is a leader in conducting research studies and clinical trials to better understand and treat cardiovascular disease.

To refer a patient, please contact the study or trial coordinator or email VascularSurgeryResearch@upmc.edu.

For more information about the UPMC Heart and Vascular Institute, please call 412-802-3333 or visit UPMC.com/HVI.

**Zenith® p-Branch™ Pivotal Study:**
Clinical investigation intended to evaluate the safety and effectiveness of the Zenith® p-Branch™ in combination with Atrium iCAST™ covered stents for the treatment of pararenal or juxtarenal aortic aneurysms.

**Inclusion criteria:** Patients with a pararenal or juxtarenal abdominal aortic aneurysm (AAA) ≥ 5.0 cm in diameter with anatomy suitable for treatment with the Zenith® p-Branch™.

**Principal Investigator:** Michael Singh, MD
**Contact:** Caroline Kissell, 412-235-1304

**PRESEVERE-Zenith® Iliac Branch Clinical Study:**
Clinical study to evaluate the safety and effectiveness of the Zenith® Branch Endovascular Graft-Iliac Bifurcation.

**Inclusion criteria:** Patients with an aortoiliac or iliac aneurysm, an insufficient distal sealing site within the common iliac artery, and having morphology suitable for endovascular repair.

**Principal Investigator:** Michael Singh, MD
**Contact:** Caroline Kissell, 412-235-1304

**BEST-CLI Trial:**
Randomized, multicenter, controlled trial to compare best endovascular versus best surgical therapy in patients with critical limb ischemia.

**Inclusion criteria:** Infrainguinal arterial occlusive disease and critical limb ischemia (CLI) – arterial insufficiency with gangrene, non-healing ischemic ulcer, or rest pain consistent with Rutherford categories 4-6. Atherosclerotic, infrainguinal PAD. Candidate for both open and endovascular infrainguinal revascularization.

**Principal Investigator:** Rabih Chaer, MD
**Contact:** Ali Arak, 412-623-8443

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Critical Limb Ischemia (CLI) in Patients with Femoropopliteal Occlusive Disease Treated with Drug Coated Balloon (DCB) Angioplasty:
Pilot study to evaluate if there is a direct association between paclitaxel and wound healing in patients with CLI.

Inclusion criteria: Femoropopliteal arterial occlusive disease and CLI with tissue loss (Rutherford Classification of 5 or 6). All activities are standard of care with the exception of sending the debrided tissue sample for specialized staining to evaluate for paclitaxel crystals.

Principal Investigator: Rabih Chaer, MD
Contact: Ali Arak, 412-623-8443

Registry of Transcarotid Artery Revascularization (TCAR) in Patients with Significant Carotid Artery Disease:
Registry to confirm the safety and effectiveness of the less-invasive TCAR procedure using the ENROUTE® Transcarotid Neuroprotection and Stent System to provide cerebral (brain) embolic protection during carotid artery revascularization in subjects at high risk for complications from traditional CEA. The TCAR procedure temporarily reverses blood flow to the brain during the carotid intervention to reduce the incidence of procedural embolic stroke while delivering balloons and a stent to stabilize the plaque to prevent a future stroke. All procedures are standard of care. Study follow-up is one month in duration.

Principal Investigator: Rabih Chaer, MD
Contact: Caroline Kissell, 412-235-1304

Standard vs. UltrasouNd-asSisted CathEter Thrombolysis for Acute Submassive Pulmonary Embolism (SUNSET sPE) Trial: Randomized trial on intermediate risk pulmonary embolism comparing standard catheter vs. ultrasound assisted thrombolysis. The Pulmonary Embolism Response Team (PERT) of UPMC has recently started actively enrolling patients.

Principal Investigators: Efthymios Avgerinos, MD and Rabih Chaer, MD
Contact: Ali Arak, 412-623-8443

Penumbra Extract- PE
Clinical investigation intended to evaluate the safety and effectiveness of the Penumbra Indigo Aspiration system for mechanical thrombectomy treatment of acute Submassive pulmonary embolism (PE)

Inclusion criteria: Patient is 18 years of age or older with symptomatic acute PE with duration of 14 days or less. Systolic BP ≥90 mmHg with evidence of dilated RV with an RV/LV ratio >0.9.

Principal investigator: Efthymios Avgerinos, MD
Contact: Ali Arak 412-623-8443

GORE® TAG® Thoracic Branch Endoprosthesis
A prospective, non-randomized study to evaluate the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) in the treatment of lesions of the aortic arch and the descending thoracic aorta.

Inclusion criteria: Patients > 18 years of age with thoracic aortic lesions which require coverage of the left subclavian artery, left common carotid artery and/or the brachiocephalic trunk/innominate artery for effective treatment and have anatomy suitable for treatment with the TAG® TBE Device

Principal Investigator: Dr. Michael Singh
Contact: Caroline Kissell 412-235-1304

GORE® EXCLUDER® Conformable AAA Endoprosthesis
A prospective, non-randomized study to assess the safety and effectiveness of the CEXC device for the treatment of infrarenal AAA. The CEXC device will allow endovascular treatment in hostile infrarenal aortic anatomy characterized by either a short proximal seal zone and/or excessive proximal neck angulation.

Inclusion criteria: Patients > 21 years of age with a AAA that meet any of the following criteria • Maximum diameter ≥ 50 mm • Rapid growth (> 5 mm in a 6 month period) or • Non-ruptured AAA presenting with clinical symptoms and have anatomy suitable for treatment with the CEXC device.

Principal Investigator: Dr. Al-Khoury
Contact: Caroline Kissell 412-235-1304