UPMC Heart and Vascular Institute
Division of Vascular Surgery - Clinical Research - Enrolling Studies

study name	Study title/sponsor	study population	study rationale	study design
Investigator Initiated Studies				
Screening for HPR	The Value of Screening for "High on Treatment Platelet Reactivity" in Patients Undergoing Lower Extremity Arterial Endovascular Interventions	Patients with lower extremity arterial disease undergoing balloon angioplasty or stenting of the superficial femoral artery or popliteal artery.	Screening for HPR in patients with symptomatic peripheral arterial disease undergoing angiography will identify patients who are non-responsive to clopidogrel and tailoring antiplatelet therapy using ticagrelor will improve patency of femoropopliteal interventions.	Open label randomized controlled trial comparing screening and treating for HPR versus no testing with guidline-based care in patients with lower extremity arerial disease undergoing balloon angioplasty or stenting of superficial femoral artery or popliteal artery.
RIGEL	Randomized Trial of Fistula Versus Graft in Elderly Patients Pilot Study	Patients over 65 years of age who start hemodialysis with a TDC and are eligible to receive either AVF or AVG.	The goal of this project is to have a significant impact on how surgeons select dialysis access for elderly patients already on hemodialysis, with eventual influence on guidelines, policies, and fiscal endpoints.	Open-label pilot randomized controlled trial to test the feasibility and safety of randomizing patients over 65 years old who start hemodialysis with a TDC and are eligiable to receive either AVF or AVG.
Vein Biomarkers	Biomarkers that Define Severity of Chronic Venous Insufficiency	Patients who present to the clinical setting of the vascular surgeon with diagnosis of venous disease and are determined to be CEAP 2-6 will be considered potential research subjects.	Venous ulceration can be predicted using biomarkers. We predict that certain inflammatory biomaerks will be elevated in pateints who present with active ulceration, and in patients who will develop an ulcer within one year.	Descriptive, observational, longitudinal study to determine if severe venous disease can be predicted by blood biomarkers. To accomplish this, we will be looking at biomarkers for patients who present with both severe and less severe cases of venous insufficiency.
HMGB1	Inflammasome Activation and HMGB1 Release Mechanisms in Peripheral Arterial Disease	Patients undergoing lower extremity amputation including below knee amputation or above knee amputation.	We believe that ischemic muscle in peripheral arterial disease pateints releases exosomes that carry HMGB1 within them, and are released through caspase-1 mediated pathways.	
Inflammation in Venous Disease	Damage Associated Molecular Patterns and Inflammation in Venous Disease	Patients undergoing scheduled stab plebectomy, bypass surgery with saphenous vein, or dialysis access	Evaluation of inflammation in varicose veins to assess leukocyte trapping and endothelial inflammation as a potential contributor to venous hypertension.	Bio-specimen study which will seek to find out if inflammation plays a role in varicose vein disease through the use of immunofluorescence, RNA microarray, and scRNA sequencing preformed on discarded vein tissue.
Physician Resilience	Physical Activity and Stress Mangement to Improve Personal Resilience Among the Physicians of the UPMC Heart and Vascular Institute	Cardiologists, Cardiac Surgeons, and Vascular Surgeons which constitute the physicians of the UPMC Heart and Vascular Institute (HVI)	The goal of this project is to assess the impact of physical activity coaching on resilience and wellbeing of the physicians of UPMC HVI.	Observational, open-label study to measure physician resilience in the setting of cardiology and vascular surgery.
AAA Healing After EVAR	Identification of Biomarkers of Aortic Aneurysm Growth and Healing following EVAR	Patients presenting to UPMC for AAA repair who are appropriate for EVAR	Identifying the differential expression of circulating biomarkers after EVAR in those with regressing, stable, and expanding aneurysms will identify pathophysiologic mechanisms of aneurysm behavior not previously studied with aneurysm growth alone.	
SFA POP	Evaluate the effects of paclitaxel on wound healing for patients with CLI and tissue loss	Patients (40 - 95) with CLI and tissue loss, Rutherford category of 5 or 6; treated with either the Bard Lutonix or the Medtronic Admiral balloon	To evaluate the paclitaxel level in debrided tissue following DCB (drug coated balloon) angioplasty for femoropopliteal occlusive disease in patients with CLI (critical limb ischemia) and tissue loss to see if it impacts wound healing	Prospective, single center non-randomized, single arm clinical trial

UPMC Heart and Vascular Institute
Division of Vascular Surgery - Clinical Research - Enrolling Studies

study name	Study title/sponsor	study population	study rationale	study design
Industry Sponsored				
AAA 13-03	Assessment of the GORE EXCLUDER Conformable AAA Endoprosthesis in the Treatment of Abdominal Aortic Aneurysms	Subjects with infrarenal abdominal aortic aneurysms	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	Prospective, nonrandomized, multicenter study with two parallel sutstudies: Short neck substudy (neck ansulation ≤ 60 degrees and infrarenal aortic neck length ≥ 10 mm. High neck angulation substudy: aortic angulation > 60 and ≤ 90 and infrarenal aortic neck length ≥ 10 mm
SSB-1102 Pivitol	Evaluation of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE Device) in the Treatment of Lesions of the Aortic Arch and Descending Thoracic Aorta	Subjects with thoracic aortic lesions which require coverage of the left cubclavian artery, left common carotid artery and/or the brachiocephalic trunk/innominate artery for effective treatment	Determine whether the GORE TAG Thoracic Branch Endoprosthesis is safe and effective in treating lesions of the aortic arch and descending thoracic aorta	Prospective, nonrandomized, multicenter study with four independent arms consisting of a total of seven cohorts: Zone 2 - aneurysm, Zone 2 - non-aneurysm (dissection, traumatic transection, other isolated lesions), Zone 0/1 Aneurysm, Zone 0/1 non-aneurysm (dissection, other isolated lesions)
TAMBE 17-01	Evaluation of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in the Treatment of Thoracoabdominal and Pararenal Aortic Aneurysms	Subjects with thoracoabdominal or pararenal aneurysms requiring treatment. Primary study arm: Adapted Crawford Type IV TAA and Pararenal Aneirusms. Secondary Study Arm: Adapted crawford Type I-III	Assess the safety and effectiveness of the TAMBE Device in the treatment of thoracoabdominal and pararenal aortic aneurysms	Prospective, non-randomized, , multicenter study with two independent arms: •Primary Study Arm – TAAA requiring only TAMBE System. Hypothesis-driven analysis. •Secondary Study Arm – TAAA requiring TAMBE System and CTAG Device(s). Non-hypothesis-driven analysis.
Detour 2	The Detour Endovascular Technique for long Occlusive fem-pop revascularization - 2	Rutherford 3 to 5, Complex TAASC C and TASC D lesions, reference vessel diameter 4.5-6.7 mm	The safety and effectiveness of the PQ Bypass Systemm will be established by comparing the primary safety and effectiveness endpoints in th eIDE Study to safety and effectiveness Performance Goals	Prospective, single-arm, multi-center, iinternational clinical investigation to evaluate the safety and effectiveness of the PQ Bypass System to access, deliver guidewires, and implant stant grafts for percutaneous femoropopliteal bypass
RESCUE	Recombinant tPA by Endovascular Administration for the treatment of Submassive Pulmonary embolism using pharmaco-mechanical Catheter directed thrombolysis for the reduction of thrombus burden	patients 18- 75 years of age who present with symptoms of acute submassive PE within 14 days of onset of symptoms will be considered	to demonstrate the efficacy and safety of the Bashir Endovascular Catheter for the administration of pharmaco-mechanical catheter directed therapy using low dose r-tPA for the treatment of acute submassive PE	Prospective, non-randomized, multi-center study
C-TRACT	Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy	Patients with moderate to severe post-thrombotic syndrome	Determine if the use of imaging-guided endovascular intervention is an effective strategy with which to improve QOL and reduce PTS symptom severity in patients with established SIO-PTS	Multicenter, parallel two-arm, open-label, assessor-blinded, randomized (1:1) clinical trial : endovascular therapy + standard PTS therapy versus standard PTS therapy alone.
BEST-CLI Registry	BEST - Real World Outcomes in Critical Limb Ischemia Registry	Patients with infrainguinal peripheral artery disease and critical limb ischemia consistene with Rutherford categories 4-6	Patients in the BEST-Registry will be enriched for diabetes, cardiac, pulmonary and renal comorbidities relative to BEST-CLI patients.	Prospective, multicenter registry evaluating the real-world therapeutic strategies, clinical outcomes, and costs associated with patients presenting with critical limb ischemia.
LIFE-BTK	Pivotal Investigation of safety and efficacy of BRS treatment - below the knee	Subjects from all genders with arterial narrowing in the infrapopliteal lesions causing critical limb ischemia.	ESPRIT BTK has the potential to provide superior outcomes to PTA by providing: 1. vessel scaffolding thus preventing acute recoil; 2. elution of everolimus, thus preventing arterial re-narrowing and reducing the risk of revascularization; 3. preservation of additioanl treatment option for treated vessel thanks ot scaffold resorption over time.	Prospective, randomzed, single-blind, multi-center clinical investigation