St. Joseph Hospital Heart and Vascular Center

CLINICAL TRIALS AND RESEARCH PROGRAM

Candidates' Condition	Clinical Trials Open for Enrollment	Investigators
Patients with moderate aortic stenosis and in heart failure with EF less than 50% and New York Heart Association class II to IV despite optimal heart failure treatment	**TAVR UNLOAD:** Transcatheter Aortic Valve Replacement to Unload the Left ventricle in patients with Advanced heart failure: a randomized trial Sponsor: Cardiovascular Research Foundation (CRF)	Principal Investigator: *Brian Kolski, MD* Co-Investigator: *Aidan Raney, MD*
Patients in acute MI with cardiogenic shock	**NCSI:** National Cardiogenic Shock Initiative Investigator-initiated Study	Principal Investigator: *Brian Kolski, MD*
Patients with moderate to severe post thrombotic syndrome and ipsilateral iliac vein obstruction	**C-TRACT:** Chronic Venous Thrombosis: Relief with Adjunctive Catheter-Directed Therapy Sponsor: National Institute of Health (NIH)/ Washington University	Principal Investigator: *Mahmood Razavi, MD* Co-Investigators: *Kurt Openshaw, MD;* *Tiffany Wu, MD;* *Stacey Tien, PA-C*

Patients with dysfunctional dialysis AV Fistula	**Lutonix AV PAS:** A Prospective, Global, Multicenter, Single Arm Post-Approval Study Investigating the Clinical Use and Safety of the Lutonix® Drug Coated Balloon PTA Catheter for the Treatment of Dysfunctional AV Fistulae Sponsor: Lutonix	Principal Investigator: *Mahmood Razavi, MD* Co-Investigators: *Kurt Openshaw, MD;* *Bhavraj Khalsa, MD*

Patients with critical limb ischemia, Rutherford-Becker clinical category classification 4 or 5	**Illumenate BTK:** Prospective, Randomized, multi-Center Study to evaluate treatment of subjects with occlusive Disease with a novel Paclitaxel-coated Angioplasty Balloon in Below-The-Knee (BTK) arteries Sponsor: Philips/Spectranetics	Principal Investigator: *Tiffany Wu, MD* Co-Investigators: *Mahmood Razavi, MD;* *Kurt Openshaw, MD;* *Daniel Flanigan, MD;* *Bhavraj Khalsa, MD*
Patients with de novo, calcified coronary artery lesions presenting with stable, unstable or silent ischemia that are suitable for percutaneous coronary intervention.	**Disrupt CAD III:** Prospective, Multicenter, Single-Arm, Global IDE Study of the Shockwave Coronary Intravascular Lithotripsy (IVL) System with the Shockwave C2 Coronary IVL Catheter in Calcified Coronary Arteries Sponsor: Shockwave Medical	Principal Investigator: *Brian Kolski, MD* Co-Investigator: *Aidan Raney, MD;* *Michael Chan, MD*

Patients with thrombosis in the peripheral vasculature.	**CAPERE Thrombectomy post market study:** Prospective, single-arm, non-blinded study, intending to collect and evaluate data in subjects with acute thrombosis, treated with the CAPERE™ Thrombectomy System. Sponsor: Vascular Medcure	Principal Investigator: *Tiffany Wu, MD* Co-Investigators: *Mahmood Razavi, MD;* *Kurt Openshaw, MD*
Patients presenting with acute coronary vessel occlusion who are referred for standard of care PCI.	**CHEETAH:** A Prospective, Multicenter Study to Evaluate the Safety and Performance of the CAT RX Aspiration Catheter in Patients with a High Thrombus Burden Acute Coronary Vessel Occlusion Sponsor: Penumbra	Principal Investigator: *Brian Kolski, MD* Co-Investigator: *Aidan Raney, MD;* *Michael Chan, MD;* *Jairo Marin, MD*
Patients presenting with atherosclerotic lesions with ≥70% stenosis in superficial femoral artery or popliteal artery.	**TAP-DANCE:** Temsirolimus Alone or Paired with Dexamethasone delivered to the Adventitia to enhance Clinical Efficacy after femoropopliteal revascularization Sponsor: Mercator MedSystems	Principal Investigator: *Tiffany Wu, MD* Co-Investigators: *Mahmood Razavi, MD;* *Bhavraj Khalsa, MD*

Humanitarian Device Exemption (HDE) Studies*

Candidates' Condition / Device Use	Clinical Trials Open for Enrollment	Authorized Physicians
Indicated for use with embolic coils for the treatment of wide-neck, intracranial saccular aneurysms.	**NEUROFORM:** Microdelivery Stent System HDE Holder: Stryker	*Mahmood Razavi, MD*
Indicated for use in the treatment of free perforations.	**GraftMaster"** GraftMaster Coronary Stent Graft HDE Holder: Abbott Vascular	*Donald Mahon, MD;* *Tyson Cobb, MD;* *Lawrence Santora, MD;* *George Wesley, MD;* *Jairo Marin, MD;* *Michael Chan, MD;* *Brian Kolski, MD;* *Aidan Raney, MD;* *Mahmood Eslami, MD;* *Ethan Yalvac, MD;* *Raveen Arora, MD;* *Ravi Jandhyala, MD;* *Ameesh Parikh, MD;* *Christopher Lo, MD;* *Mahmood Razavi, MD;* *Bahram Eslami, MD*

Indicated for use with embolic coils for the treatment of wide-neck, intracranial, saccular or fusiform aneurysms.	**ENTERPRISE:** Enterprise Vascular Reconstruction Device and Delivery System HDE Holder: Codman Neuro	*Mahmood Razavi, MD*
Indicated for use with embolic coils for treatment of wide-neck, intracranial, unruptured aneurysms, originating on or near a vessel bifurcation of the basilar tip or carotid terminus.	**PulseRider:** PulseRider® Aneurysm Neck Reconstruction Device HDE Holder: Codman Neuro	*Mahmood Razavi, MD*
Indicated for the treatment of acute perforations of native coronary arteries and coronary bypass grafts.	**PK Papyrus:** Balloon-expandable covered stent pre-mounted on a fast-exchange delivery system HDE Holder: Biotronik	*Donald Mahon, MD;* *Tyson Cobb, MD;* *Lawrence Santora, MD;* *George Wesley, MD;* *Jairo Marin, MD;* *Michael Chan, MD;* *Brian Kolski, MD;* *Aidan Raney, MD;* *Mahmood Eslami, MD;* *Ethan Yalvac, MD;* *Raveen Arora, MD;* *Ravi Jandhyala, MD;* *Ameesh Parikh, MD;* *Christopher Lo, MD;* *Bahram Eslami, MD*

* Innovative medical devices to treat or diagnose rare diseases are developed through Humanitarian Device Exemption Studies. These clinical trials offered by the St. Joseph Hospital Heart and Vascular Center involve Humanitarian Use Devices (HUDs) in which safety and probable benefit have been verified.

Candidates' Condition	Clinical Trials Closed for Enrollment*	Investigators
Patients presenting with symptoms of acute pulmonary embolism.	**EXTRACT-PE:** A Prospective, Multicenter Trial to Evaluate the Safety and Efficacy of the Indigo® Aspiration System in Acute Pulmonary Embolism Sponsor: Penumbra	Principal Investigator: *Mahmood Razavi, MD* Co-Investigator: *Kurt Openshaw, MD*
Patients with upper body venous occlusions or other conditions that preclude central venous access by conventional methods.	**SAVE US Surfacer System:** Evaluation of the Surfacer® System Approach to Central Venous Access Sponsor: Bluegrass Vascular	Principal Investigator: *Mahmood Razavi, MD* Co-Investigator: *Kurt Openshaw, MD*
Patients who require treatment of a non-malignant venous obstruction within the common iliac, external iliac and/or common femoral vein.	**ABRE:** A multi-center, non-randomized study to evaluate the safety and effectiveness of the Abre venous self-expanding stent system in patients with symptomatic iliofemoral venous outflow obstruction Sponsor: Medtronic	Principal Investigator: *Mahmood Razavi, MD* Co-Investigator: *Kurt Openshaw, MD*

Patients who have chronic obstruction of common femoral, external iliac, or common iliac veins.	**VIRTUS:** Safety and Efficacy of the Veniti Vici™ Venous Stent System when Used to Treat Clinically Significant Chronic Non-malignant Obstruction of the Iliofemoral Venous Segment Sponsor: Veniti/Boston Scientific	Principal Investigator: *Mahmood Razavi, MD* Co-Investigators: *Kurt Openshaw, MD;* *Stacey Tien, PA-C*
Patients with obstructive atherosclerotic lesions in below knee popliteal, tibial, or peroneal arteries	**TANGO:** Temsirolimus adventitial delivery to improve angiographic outcomes below the knee Sponsor: Mercator MedSystems	Principal Investigator: *Mahmood Razavi, MD* Co-Investigators: *Tiffany Wu, MD;* *Daniel Flanigan, MD;* *Stacey Tien, PA-C*

* These clinical trials remain active but are no longer accepting new patients.