MICHIGAN MEDICINE
UNIVERSITY OF MICHIGAN

VENOUS CLINICAL TRIALS

GORE VNS 21-05
Drs. Khaja/Sherk

Study Objective
Establish the safety and effectiveness of the GORE® VIAFORT Vascular Stent for treatment of symptomatic IVC obstruction w /or w/o combined iliofemoral obstruction.

Primary Inclusion Criteria
Presence of non-malignant obstruction of the IVC defined as occlusion or at least 50% reduction in target vessel lumen as measured by procedural IVUS and venogram, w /or w/o nonmalignant obstruction of the common femoral, external, and/or common iliac veins.

GORE VNS 21-07
Drs. Sherk/Khaja

Study Objective
Establish the safety and effectiveness of the GORE® VIAFORT Vascular Stent for treatment of symptomatic iliofemoral obstruction.

Primary Inclusion Criteria
Presence of non-malignant unilateral obstruction of the common femoral, external, and/or common iliac veins defined as occlusion or at least 50% reduction in target vessel lumen as measured by procedural IVUS and venogram.

BOSTON SCIENTIFIC STENT THROMBOSIS
Dr. Khaja

Study Objective
The purpose of this study is to better understand the myriad of factors that cause stent thrombosis and identify those patients who would best be served by a thrombolysis strategy versus venoplasty and re-stenting.

The study will collect two-three additional biospecimen tissue samples from patients with in-stent thrombosis.

Primary Inclusion Criteria
Adult Patients who are undergoing revascularization of thrombosed venous stents, acute or chronic.

ADIENT ABSORBABLE IVC FILTER
Dr. Khaja

Study Objective
Prospective, multicenter, pivotal study w/ randomized controlled prophylactic & therapeutic cohorts to evaluate the safety & efficacy of the Adient Absorbable VCF for PE prevention compared to best practice-VTE prophylaxis.

Primary Inclusion Criteria
For the prophylactic cohort, high risk VTE denoted by either:
- Caprini score > 8 for surgical ICU
- Parvizi score ≥ 150 for TKA
- ISS score ≥ 24 for trauma

For the therapeutic cohort, documented VTE when anticoagulants are contraindicated:
- Failure of anticoagulant therapy in VTE
- Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced

NIH SPONSORED PE-TRACT TRIAL
Dr. Khaja

Study Objective
Multicenter, assessor-blinded, RCT w/1:1 randomization to determine if patients with submassive PE who are treated w/ catheter directed therapy (CDT) have better cardiopulmonary health (at 3 months via CPET & patient-reported functional capacity at 12 months via NYHA status) in the year following PE than patients treated with No-CDT. All patients will be treated with anticoagulation.

Primary Inclusion Criteria
- Symptomatic acute intermediate-risk PE (<14 days) diagnosed by CTA with involvement of a main or lobar pulmonary artery *and*
- Right ventricular dilation w/ RV/LV ratio > 1 on CTA
- CDT may include thrombectomy or thrombolysis w/FDA approved technologies

Faculty:
Minhaj Khaja, MD, MBA
William Sherk, MD