ONGOING CLINICAL TRIALS

TRANSPLANT AND INPATIENT TRIALS

A randomized, open-label, multi-center trial to determine safety and efficacy of eculizumab in the prevention of antibody mediated rejection (AMR) in living donor kidney transplant recipients requiring desensitization therapy.  
Principal Investigator:  Joseph Buell, MD

The Effect of Zortress (everolimus) on Glucose Metabolism and Post-Transplant Diabetes in Kidney Transplant Patients.  
Principal Investigator:  Douglas Slakey, MD

A phase 2A, randomized, open-label, active control, multi-center study to assess the efficacy and safety of ASKP1240 in De Novo kidney transplant recipients.  
Principal Investigator:  Mary Killackey, MD

A three-part, multi-center, randomized, double-blind, placebo-controlled, parallel-group, sequential adaptive, phase II study to evaluate the safety, tolerability and efficacy of OPN-305, a humanized, monoclonal antibody that blocks toll-like receptor 2, in renal transplant patients at high risk of delayed graft function.  
Principal Investigator:  Mary Killackey, MD

Belatacept Evaluation of Nephroprotection and Efficacy as First-line Immunosuppression Trial - EXTended Criteria Donors  
Principal Investigator:  Rubin Zhang, MD

A phase III, randomized, multicenter, double-blind, double-dummy, parallel-group, comparative study to determine the efficacy, safety, tolerability of Ceftazidime-Avibactam (CAZ-AVI) plus Metronidazole versus meropenem in the treatment of complicated intra-abdominal infections (CIAIs) in hospitalized adults.  
Principal Investigator:  Douglas Slakey, MD

GENERAL SURGERY TRIALS

A prospective, single-blind, randomized, phase III study to evaluate the safety and efficacy of Fibrin Sealant Grifols (FS Grifols) as an adjunct to hemostasis during Parenchymous Tissue open surgeries.

Continued on next page
Principal Investigator: Joseph Buell, MD

Key Inclusion Criteria:
- 18 years or older.
- Require an elective (non-emergency), liver resection

*A Prospective, Single-blind, Randomized, Phase III Study to Evaluate the Safety and Efficacy of Fibrin Sealant Grifols (FS Grifols) as an Adjunct to Hemostasis during Peripheral Vascular Surgery.*

Principal Investigator: Anil Paramesh, MD

Key Inclusion Criteria:
- 18 years or older.
- Require one of peripheral vascular procedures listed below:
  1. Femoral-femoral bypass grafting.
  2. Femoral-popliteal bypass grafting.
  3. Femoral-distal bypass grafting.
  4. Ilio-iliac bypass grafting.
  5. Ilio-femoral bypass grafting.
  6. Ilio-popliteal bypass grafting.
  7. Upper extremity vascular access for hemodialysis.

*A Randomized, Double-Blind, Placebo-controlled Efficacy, Safety, and Tolerability Study of up to 20 mL of DFA-02 in Patients Undergoing Abdominal Surgery*

Principal Investigator: Clifton McGinness, MD

Key Inclusion Criteria:
- 18 years or older.
- Require non-emergent abdominal surgery involving a planned incision of 7 cm or greater. List of eligible procedures: left, right or transverse colectomy, segmental/sleeve left colon resection, total abdominal colectomy with ileorectal anastomosis, total abdominal colectomy with ileostomy, total abdominal proctocolectomy, low anterior resection, sigmoid resection, non-emergent Hartmann's procedure, colotomy with polypectomy distal to hepatic flexure, colostomy takedown through laparotomy, ileo-pouch anal anastomosis and abdominal perineal resection of the rectum, open repair of ventral hernia, hepaticojjunostomy, gastrojejunostomy pancreaticojejunostomy, and bile duct reconstruction.

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