SOUTH JERSEY
MEDICAL REPORT™

Clinical Trials

More than 450 clinical trials, including national trials, are currently underway at Cooper University Health Care, addressing a wide-range of novel pharmacologic, surgical and device-related therapeutic options. Cooper's robust research program offers clinicians and their patients access to some of the most novel therapies and innovative trials in the region.

The following list represents some of the clinical trials currently enrolling patients at Cooper.

Spring 2014

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Anesthesia	Marc Torjman, PhD	Ashley S. 856.968.7333	Device	Primary objective is to evaluate the safety, accuracy and performance of study glucose monitoring device in hospitalized patients.	1. Age ≥ 21 years. 2. Diabetic and non-diabetic patients with an anticipated stay > 24 hours of admission to intensive care. 3. Patient understands and signs informed consent document.
Anesthesia	Michael E. Goldberg, MD	Ashley S. 856.968.7333	Drug	Evaluate the efficacy of pregabalin compared with placebo in the treatment of chronic post-traumatic peripheral neuropathic pain.	1. Must be 18 years of age and have and be able to use a telephone. 2. Have chronic peripheral neuropathic pain greater than 6 months post surgical or traumatic event. 3. Must meet criteria for neuropathic pain assessment per protocol.
Cooper Bone and Joint Institute Rheumatology	Kwanghoon Han, MD	Amanda L. 856.968.7615	Drug	To see if belimumab when given with azathioprine is safe and effective in keeping vasculitis disease under control or remission.	1. At least 18 years of age. 2. Have a diagnosis of Wegner's granulomatosis (WG) or microscopic polyangitis (MPA). 3. Have had a recent (within last 26 weeks) episode of moderate to severely active WG or MPA that required treatment.
Cooper Neurological Institute Neurology Huntington's Disease	Amy Colcher, MD	Cory H. 856.342.2460	Drug	Evaluates the efficacy of a drug in slowing the functional decline in early Huntington's Disease (HD) patients.	1. Males or Females ≥ 18 years of age. 2. Clinical features of HD and confirmatory familial history of HD or clinical features of HD and a CAG repeat length ≥ 36. 3. Stage I or II HD (TFC > 7) and ambulatory.
Cooper Neurological Institute Neurology Intraventricular Hemorrhage	Thomas R. Mirsen, MD	Tamara L. 856.968.7222	Drug	Evaluation study of early intervention of extraventricular drain use and recombinant tissue plasminogen activator for the treatment of intracerebral and intraventricular hemorrhage.	1. Spontaneous ICH ≤ 30 cc and IVH obstructing 3rd and/or 4th ventricles. 2. Between 18 and 80 years old.
Cooper Neurological Institute Neurology Transient Ischemic Attack and Minor Ischemic Stroke	Thomas R. Mirsen, MD	Tamara L. 856.968.7222	Drug	Evaluates the safety and efficacy of a drug therapy for prevention of reoccurring ischemic event.	1. Males or females over 18 years of age. 2. High risk TIA, or minor ischemic stroke.
Gynecologic Oncology Ovarian, Peritoneal or Fallopian Tube Cancer	David P. Warshal, MD	Maria D. 856.325.6733	Drug	Evaluates diet and exercise to determine its effect on progression free survival in women who have completed treatment for ovarian, primary peritoneal or fallopian tube cancer and are cancer free.	1. All Stage II to Stage IV women who have completed primary therapy with or without consolidation at least 6 weeks but no more than 6 months from last date of treatment. 2. Documented complete response based on normal CA 125 and CT scan or MRI with contrast. 3. No other chronic disease that might interfere with the lifestyle intervention.
Gynecologic Oncology Recurrent Ovarian Cancer	David P. Warshal, MD	Maria D. 856.325.6733	Drug	Placebo-controlled study evaluating the effectiveness of an investigational agent that is thought to stop the formation of blood vessels within a tumor and to potentially stop tumor growth.	1. The drug or placebo will be given weekly with standard therapy for first line treatment using Taxol/Carbo. 2. After 6 cycles, the investigational agent/placebo will be given weekly for an additional 18 cycles. 3. Newly diagnosed Stages III-IV epithelial ovarian, fallopian or peritoneal cancer, generally well controlled blood pressure, and no previous treatment.
Hematology/Oncology Breast Cancer	Robert A. Somer, MD	Kimberly K. 856.735.6237	Drug	Evaluates the effect of adding a new anti-HER2 drug, pertuzumab, to treatment with traztuzumab and an aromatase inhibitor.	1. Metastatic HER2 Positive breast cancer. 2. Post menopausal. 3. No previous therapy for metastatic breast cancer.
Hematology/Oncology Colon Cancer	Robert A. Somer, MD	Kimberly K. 856.735.6237	Drug	To determine if adding 3 years of treatment with a COX-2 inhibitor to standard chemotherapy for colon cancer can improve patient outcomes.	1. Surgically resected colon cancer. 2. At least 1 positive lymph node. 3. No history of upper GI ulceration, bleeding or perforation within past 3 years.
Hematology/Oncology Lung Cancer	Robert A. Somer, MD	Kimberly K. 856.735.6237	Drug	Evaluates the effect of treatment with chemotherapy with or without bevacizumab after surgery for early stage non-small cell lung cancer.	1. Surgically resected stage IB to IIIA non small cell lung cancer. 2. Between 6 and 12 weeks out from definitive surgery. 3. No prior anti-cancer treatment.
Medicine Cardiovascular Disease	Fredric L. Ginsberg, MD	Amanda L. 856.968.7615	Device	To see if chronic stimulation of the phrenic nerve will reduce or prevent apnea episodes.	1. At least 18 years of age. 2. Central Sleep Apnea confirmed by sleep study. 3. Medically stable for 30 days prior to baseline testing.
Medicine Cardiovascular Disease Atrial Fibrillation (AFib)	Andrea M. Russo, MD	Julie F. 856.968.7032	Treatment	Comparison study of drug treatment verses ablation for atrial fibrillation.	1. Male or females over 18 years of age. 2. Have a documented Afib. 3. Warrant active therapy beyond observation.
Radiation Oncology Pancreas Cancer	Tamara A. LaCouture, MD	Dana O. 856.735.6233	Radiation	Evaluates the percentage of patients able to successfully undergo pancreaticoduodenectomy after radiation.	1. Resectable or potentially resectable adenocarcinoma of the pancreas. 2. No prior radiation to the upper abdomen. 3. Must be able to undergo MRI with contrast.

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Medicine Cardiovascular Disease Pacemaker	Andrea M. Russo, MD	Julie F. 856.968.7032	Device	To demonstrate that MRI can safely be done with subjects who have these newly implanted pacemakers without any harm to the pacemaker system or the subject.	1. Male or females over 18 years of age. 2. Have an indication for an implantable pacemaker. 3. Able to get a MRI.
Medicine Cardiovascular Disease Peripheral Vascular Disease	Janah Aji, MD	Leana A. 856.342.2648	Drug	Evaluates the safety and tolerability of long term antiplatelet therapy in patients with established Peripheral Artery Disease (PAD).	1. Male or females over 50 years of age. 2. Symptomatic PAD (leg pain with exertion associated with physical limitations from PAD). 3. Prior lower extremity revascularization.
Medicine Cardiovascular Disease Peripheral Vascular Disease	Janah Aji, MD	Leana A. 856.342.2648	Device	A randomized blinded trial evaluating the safety and effectiveness of a new bioresorbable vascular scaffold in the treatment of subjects with new native coronary artery lesions.	1. Male or females age 18 or older. 2. Undergoing Coronary artery stenting. 3. Evidence of myocardial ischemia, suitable for elective PCI.
Medicine Critical Care	Stephen W. Trzeciak, MD	Lisa P. 856.298.3754	Observation	To determine neurological and cognitive effects of hyperoxia after cardiac arrest.	1. Cardiac arrest. 2. Intent to treat with targeted temperature management.
Medicine Critical Care	Stephen W. Trzeciak, MD	Lisa P. 856.298.3754	Drug	To investigate the efficacy of L-carnitine as adjunctive treatment of septic shock.	1. Septic shock. 2. Lactate >2mMol/L.
Medicine Critical Care Septic Shock	R. Phillip Dellinger, MD	Christa S. 856.669.1851	Device	Evaluates the use of a hemoperfusion cartridge (adsorbs endotoxin) in a randomized controlled trial of adults with endotoxemia and septic shock.	1. Sepsis (proven/suspected) on IV antibiotics. 2. Shock - on vasopressors > 2 hours.
Medicine Critical Care Severe Sepsis	R. Phillip Dellinger, MD	Christa S. 856.669.1851	Drug	Assesses the safety and efficacy of a drug therapy in resolving organ dysfunction and reducing mortality in adults with severe sepsis and coagulopathy.	1. Severe sepsis on IV antibiotics. 2. INR > 1.4. 3. Requiring mechanical ventilation and or vasopressors.
Medicine Infectious Diseases Hematology/Oncology	Annette C. Reboli, MD	Mary P. 856.757.9783	Vaccine	Clinical trial to study the safety & efficacy of a herpes zoster vaccine.	1. Male or female > 18 years of age. 2. Solid Tumor or Hematologic Malignancy. 3. Receiving cytotoxic or immunosuppressive chemotherapy.
Medicine Infectious Diseases HCV/HIV	Pola de la Torre, MD	Yolanda S. 856.968.8651	Drug	The addition of Boceprevir to pegylated-interferon alfa 2b and ribavirin will improve hepatitis C virus treatment efficacy in HCV genotype 1-infected subjects with HCV/HIV-1 co-infection.	1. Male or female ≥ 18 years old. 2. HIV-1 infection/HCV genotype 1 coinfection. 3. Dual NRTI backbone PLUS: Efavirenze, Raltegravir, Kaletra, Atazanavir/Ritonavir, or Darunavir/Ritonavir. 4. HIV-1 RNA < 50 copies/mL.
Medicine Infectious Diseases HIV	Rosalie Pepe, MD	Cindy B. 856.968.7008	Drug	Open-label, phase IV, single-arm study in treatment-naïve HIV-1 controllers with any absolute CD4+ T-cell count to evaluate the effects of antiretroviral therapy (ART) on immune activation and inflammation, absolute CD4+ T-cell count, viral decay, residual viremia, viral reservoir, and quality of life in situations of low-level viremia.	1. Clinical diagnosis of HIV. 2. Documentation of HIV-1 RNA < 500 copies/mL verified by at least two measurements prior to the screening RNA specimen. One must be obtained ≥ 24 months, the other must be obtained < 24 months prior to screening. 3. ART naive.
Medicine Infectious Diseases HIV/Tuberculosis	Pola de la Torre, MD	Cindy B. 856.968.7008	Drug	Ultra-short-course Rifapentine/Isoniazid for the prevention of active tuberculosis in HIV-Infected individuals with latent tuberculosis infection.	1. HIV-1 infection. 2. TST reactivity ≥ 5 mm, or positive interferon gamma release assay (IGRA). 3. Never been treated for active or latent tuberculosis.
Medicine Nephrology Type II DM with Nephropathy	Christopher B. McFadden, MD	Patricia N. 856.968.7269	Drug	Drug study looking at the effect on renal outcomes in patients with type II diabetes and nephropathy.	1. Male or female age 18-85 years. 2. Have Type II DM with nephropathy.
Medicine Post MI	Behjath Jafry, MD	Patricia N. 856.968.7269	Drug	Study looking at the prevention of recurrent cardiovascular events among stable post myocardial patients with elevated hsCRP.	1. Male or female over age 18 years. 2. Documented spontaneous MI.
Obstetrics/Gynecology GYN Oncology Hysterectomy/Sexual Health	James K. Aikins, Jr., MD	Gunda S. 856.968.7547	Quality of Life	Evaluates the sexual function of women diagnosed with all forms of gynecologic cancers pre- and post-treatment.	1. Women diagnosed with a gynecological cancer (cervical, uterine, ovarian, vulvar, vaginal). 2. No prior hysterectomy. 3. No diagnosis of another type of cancer.
Obstetrics/Gynecology Female Pelvic Medicine & Reconstructive Surgery Hysterectomy/Sexual Health	Ricardo Caraballo, MD	Gunda S. 856.968.7547	Quality of Life	This study seeks to determine whether hysterectomy improves, worsens, or has no effect on sexual response.	1. Age 21 or older. 2. Candidate for abdominal or vaginal hysterectomy for a non-malignant cause.
Obstetrics/Gynecology Maternal-Fetal Medicine	Meena Khandelwal, MD	Gunda S. 856.968.7547	Assessment Best Practice	This study seeks to establish the normal deep tendon reflex measurements in pregnancy and determine if they vary by stage of pregnancy.	1. Pregnant women age16-48. 2. Non-Pregnant healthy women and men age 16-48.
Pediatrics/Neurology Adults Phenylketonuria (PKU)	Caroline Eggerding, MD	Sandra C. 856.968.7366	Drug	Open-label study to assess the safety and tolerability of an induction, titration, and maintenance dose of study drug in adults with PKU not previously treated with study drug.	1. Male or female 18-70 years old. 2. Current diagnosis of PKU. 3. If taking Kuvan treatment must end before first dose of BMN 165.

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For more information about clinical trials at Cooper, please call: Barbara C. at 856.536.1030