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 the latest 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.

Fall 2014

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Anesthesiology Abdominal Surgery	David J. Fish, MD	Ashley S. or Robyn T. 856.968.7333	Treatment Study	This is a phase 3 study to assess the efficacy and safety of Eravacycline compared to Ertapenam in complicated intra-abdominal infections.	1. Must be male or female adult over 18 years old. 2 Diagnosed with one or more intra-abdominal abscesses intervention. 3. Hospitalized and requiring abdominal surgery.
Anesthesiology and Psychiatry PTSD	Michael E. Goldberg, MD, and Basant K. Pradhan, MD	Ashley S. or Robyn T. 856.968.7333	Treatment Study	Ketamine and Mindfulness Based Cognitive Therapy (MBCT) in treatment of Post-Traumatic Stress Disorder (PTSD): Comparison of treatment efficacy and metabolomic profiles.	1. Men or women, 21-60 years of age. 2. Patients attending the outpatient psychiatry clinic of Cooper University Hospital. 3. Participants must fulfill DSM-IV criteria for current civilian or combat-related PTSD.
Anesthesiology Non Invasive Cardiac Monitoring	Ludmil V. Mitrev, MD	Ashley S. or Robyn T. 856.968.7333	Device Study	A Prospective, Nonrandomized, Noninterventional Study to Compare Study Device Cardiac Output with Thermodilution Cardiac Output.	1. Subjects must be 18 years old. 2. Subjects must be undergoing open heart surgery. 3. Subjects cannot have history of uncontrolled arrhythmias.
Cardiology Atrial Fibrillation	Andrea M. Russo, MD	Julie F. 856.968.7032	Observational Study	Investigate the differences between patients that may influence the choice of anticoagulation medication that is selected for the prevention of stroke in Atrial Fibrillation patients.	1. Must be over 18 years old. 2. Must have newly diagnosed documented Atrial Fibrillation (in the last 90 days). 3. Must be prescribed antithrombotic therapy (blood thinners) for treatment.
Cardiology Atrial Fibrillation	Andrea M. Russo, MD	Julie F. 856.968.7032	Treatment Study	Compare drug therapy and catheter ablation in patients with atrial fibrillation. This study will help decide which treatment approach is best or when one or the other therapy is preferred.	1. Must be age 18 to 90 years old. 2. Must have documented Atrial Fibrillation. 3. Must warrant therapy or treatment for Atrial Fibrillation.
Cardiology Sleep Apnea	Fredric L. Ginsberg, MD	Amanda L. 856.968.7615	Device Study	Evaluates the safety and effectiveness of therapy delivered by the study system in subjects with moderate to severe central sleep apnea (CSA) and optimal medical management.	1. At least 18 years of age. 2. Central Sleep Apnea confirmed by core lab analysis of PSG with EEG. 3. Medically stable for 30 days prior to all baseline testing (including PSG), i.e., no hospitalizations for illness, no breathing mask-based therapy, and on stable medications and therapies.
Critical Care Sepsis/Septic Shock	Stephen W. Trzeciak, MD	Lisa P. 856.928.7203	Treatment Study	To test the safety and efficacy of L-carnitine vs. placebo in patients with sepsis or septic shock.	1. Must be over 18 years old. 2. Must be vasopressor dependent for 4-24 hours. 3. Must have a lactic acid value of at least 2.0mMol/L.
Emergency Medicine Acute Coronary Syndrome	Brigitte M. Baumann, MD	Valerie B. 856.342.2637	Device Study	Compares the safety and efficacy of a 5th generation troponin assay in the diagnosis of myocardial infarction.	1. Must be 21 years of age or older. 2. Must present with symptoms suggestive of acute coronary syndrome, e.g., chest pain, pressure. 3. Must be enrolled within 24 hours of onset of symptoms.
Gynecologic Oncology	David P. Warshal, MD	Maria D. 856.325.6733	Drug Study	Evaluates the safety and efficacy of maintenance therapy with a PARP inhibitor after chemotherapy for advanced ovarian cancer in patients with BRCA mutation.	1. Females 18 years and over. 2. Stage III or IV ovarian cancer, previously treated with first-line platinum based therapy. 3. Documented mutation of BRCA1 or BRCA2 that is predicted or suspected to be deleterious.
Gynecologic Oncology	David P. Warshal, MD	Maria D. 856.325.6733	Diet and Lifestyle Study	Evaluates the effect of diet and physical activity changes on progression free survival for ovarian, fallopian tube, or primary peritoneal cancer.	1. Females 18 years and over. 2. Stage II, III or IV ovarian cancer, fallopian tube, or primary peritoneal cancer. 3. Documented complete response and normal CA-125 after treatment.
Infectious Diseases HIV	John D. Baxter, MD	Cindy B. 856.968.7008	Drug Study	Establish if HIV-1 infected adult subject with current virologic suppression on a regimen with 2 NRTIs + a third agent remain suppressed upon switching to a ABC/DTG/3tc FDC STR.	1. HIV-1 infected men or women ≥ 18 year of age. 2. Within the last year, 2 consecutive plasma HIV-1-RNA measurements < 50 c/mL and plasma HIV-1 RNA < 50 c/mL at screening. 3. Must be on a current regimen whether first or second line cART for at least 6 months prior to screening.
Infectious Diseases HIV	Rose Kim, MD	Cindy B. 856.968.7008	Vaccine Study	Understanding the basic mechanisms of the antibody response against the two types of pneumococcal vaccines in HIV + patients will help in the design of new health delivery preventative strategies in this population and other immunocompromised patients.	1. HIV-1 infected Men and women between the ages of 20-50 years old. 2. CD4 T cell count above 300 cells/ul. 3. Scheduled to receive vaccine against Streptococcus pneumonia at entry as part of standard of care.
Medical Oncology	Robert A. Somer, MD	Kim K. 856.735.6237	Drug Study	Evaluates the safety and efficacy of a new immunotherapy treatment on advanced Breast, Lung and Gastric cancers.	1. Male or female age 18 and over. 2. Locally advanced or metastatic breast, lung or gastric cancer. 3. No history of central nervous system metastases is permitted.

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Medical Oncology	Nati Lerman, MD	Kim K. 856.735.6237	Drug Study	Evaluates the safety and efficacy of a new medication for advanced or metastatic melanoma when compared to standard therapy.	1. Male or female 18 years and older. 2. Locally advanced or metastatic melanoma that is NRAS mutation positive. 3. No prior treatment for advanced/metastatic melanoma or 1 prior immunotherapy treatment.
Neurology TIA or Minor Stroke	Thomas R. Mirsen, MD	Tamara L. 856.968.7222	Drug Study	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.
Ob/Gyn	Richard L. Fischer, MD	Gunda S. 856.968.7547	Treatment Study	The purpose of this study is to assess the effectiveness of preventative antidepressants in women at increased risk for postpartum depression.	1. History of depression or postpartum depression. 2. Singleton pregnancy (must be available for screening in the third trimester). 3. Delivery at Cooper, after 34 weeks of pregnancy.
Ob/Gyn Maternal-Fetal Medicine	Meena Khandelwal, MD	Gunda S. 856.968.7547	Diagnostics Study	The purpose of this study is to develop a noninvasive prenatal test (NIPT) for fetal chromosomal abnormalities.	1. Female over 18 years of age. 2. Between 8 and 26 weeks of pregnancy. 3. At increased risk for fetal chromosomal abnormality based on age, screening, or previous or family history.
Pediatrics/Adult Medicine PKU	Caroline Eggerding, MD	Sandra C. 856.968.7366	Treatment Study	An Open Label trial to assess an injectable medication for the treatment of Phenylketonuria (PKU) in adults.	1. Must be over 16 years of age. 2. Current Phe level of >600. 3. Be willing to discontinue Kuvan treatment prior to day 1 of study injection.
Radiation Oncology	Gregory J. Kubicek, MD	Kim K. 856.735.6237	Radiation and Drug Study	Evaluates the safety and efficacy of Stereotactic body radiotherapy in conjunction with full dose chemotherapy for the treatment of unresectable stage II and stage III Non Small Cell Lung cancer (NSCLC).	1. Male or female 18 years and over. 2. Unresectable stage II or any stage III NSCLC. 3. Tumor size less than 8cm.
Radiation Oncology	Tamara A. LaCouture, MD	Kim K. 856.735.6237	Radiation and Drug Study	This study evaluates the effect of neoadjuvant chemotherapy and CyberKnife treatment on potentially resectable pancreatic cancer.	1. Male or female 18 years and over. 2. Resectable or potentially resectable adenocarcinoma of the pancreas. 3. Medically suitable for surgery.
Rheumatology	Kwanghoon Han, MD	Amanda L. 856.968.7615	Drug Study	To evaluate the efficacy of belimumab in the maintenance of remission following a standard induction regimen in subjects with Wegener's granulomatosis (WG) or microscopic polyangiitis (MPA).	1. Are at least 18 years of age. 2. Have a clinical diagnosis of Wegener's granulomatosis (WG) or a diagnosis of or microscopic polyangiitis (MPA).
Rheumatology	Kwanghoon Han, MD	Amanda L. 856.968.7615	Drug Study	To evaluate if discontinuation of methotrexate (MTX) is noninferior to continuing MTX as a strategy for maintaining disease activity in patients with rheumatoid arthritis (RA) who are inadequate responders (IR) to MTX and achieve Disease Activity Score (DAS) ≤ 3.2 following initial treatment with subcutaneous (SC) tocilizumab (TCZ) + MTX.	1. Male or non-pregnant, non-nursing female 18 years of age or older. 2. Body weight ≤ 150 kg. 3. Patients currently experiencing active moderate to severe RA (DAS28 ≥ 4.4) according to the revised 1987 American College of Rheumatology (ACR) criteria for the diagnosis of RA at screening.
Trauma Surgery Acute Spinal Cord Injury	Ju-Lin Wang, MD	Lisa C-W. 856.361.1324	Drug Study	Evaluates the safety and efficacy of drug therapy injections in adults with spinal cord injury.	1. Males or Females 18 years of age and older. 2. Non-penetrating spinal cord injury.
Trauma Surgery	Salina Wydo, MD	Lisa C-W. 856.361.1324	Drug Study	Investigates the reversal of the anticoagulant therapy after emergency surgery.	1. Males or Females 18 years of age and older. 2. History of anticoagulant therapy prior to emergency surgery.
Trauma Surgery	Joshua P. Hazelton, DO	Lisa C-W. 856.361.1324	Observational Study	Reviews the use of imaging for cervical spine injuries.	1. Males or Females 18 years of age and older. 2. Blunt Trauma. 3. Received cervical spine imaging as part of their standard of care.
Urogynecology Female Pelvic Medicine and Reconstructive Surgery	Adam S. Holzberg, DO, and/or Ricardo Caraballo, MD	Gunda S. 856.968.7547	Device Study	Two FDA/Industry-sponsored studies are being conducted to assess the long-term safety and efficacy of graft augmentation in the treatment of pelvic organ prolapse.	1. Female over 18 years of age. 2. Have pelvic organ prolapse and be seeking surgical repair.
Vascular Surgery AAA	Jose L. Trani, MD	Jonelle O. 856.342.2150	Device Study	Study the safety and efficacy of the Study Device System for Endovascular Abdominal Aortic Aneurysm (AAA) repair.	1. Abdominal aneurysm at least 5.5 cm in size. 2. At least 18 years old.
Vascular Surgery Aortic Dissection	Francis J. Caputo, MD	Jonelle O. 856.342.2150	Device Study	Evaluate safety and efficacy of the Study Dissection Endovascular System in the treatment of patients with complicated, type B aortic dissection.	1. At least 18 years old. 2. Aortic Dissection.
Vascular Surgery Critical Limb Ischemia	James B. Alexander, MD	Jonelle O. 856.342.2150	Stem Cell Study	Demonstrate the safety and efficacy of a concentrate of nucleated cells from bone marrow aspirate concentrate (BMAC) produced with the Study BMAC System for treating lower limbs of patients diagnosed with critical limb ischemia (CLI) due to peripheral arterial occlusive disease (PAOD).	1. PAOD with Rutherford 5 category disease with minor tissue loss below the ankle. 2. No open surgical or endovascular revascularization options. 3. Can not be currently on dialysis or have active malignancy.

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For more information about clinical trials at Cooper, please contact:

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