

SOUTH JERSEY MEDICAL REPORT™

Clinical Trials Over 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.

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Cardiology Coronary Artery Disease	Janah Aji, MD	Tom S. 856.968.7396	Treatment Study	This study is to compare the safety and efficacy of the trans-femoral approach to the trans-radial approach for percutaneous coronary intervention in women.	<ol style="list-style-type: none"> 1. Must be female over 18 years old. 2. Must require a coronary intervention. 3. Must be able to be randomized to transradial or trans-femoral approach.
Cardiology Coronary Artery Disease	Zoltan Turi, MD	Tom S. 856.968.7396	Device Study	This study is to compare the safety and efficacy of an arterial closure device for percutaneous coronary intervention.	<ol style="list-style-type: none"> 1. Must be over 18 years old. 2. Must require a coronary intervention. 3. Must be able to be randomized to device vs. manual pressure for arterial closure.
Cardiology Structural Heart Disease	Janah Aji, MD	Tom S. 856.968.7396	Device Study	This study is to compare the safety and efficacy of the percutaneous device for the treatment of moderate to severe symptomatic mitral regurgitation.	<ol style="list-style-type: none"> 1. Must be over 18 years old. 2. Must have moderate to severe symptomatic mitral regurgitation and be considered high risk for surgical treatment. 3. Must be able to be randomized to device vs. medical therapy for moderate to severe mitral regurgitation.
Hematology/ Oncology Breast Cancer	Robert A. Somer, MD	Kimberly K. 856. 673.4908	Drug Study	This study evaluates whether adding a new drug, BKM-120, to standard treatment with Fulvestrant improves tumor shrinkage in women with breast cancer.	<ol style="list-style-type: none"> 1. Locally advanced or metastatic Her2-negative, hormone receptor-positive breast cancer. 2. Prior treatment with an aromatase inhibitor and an mTOR inhibitor. 3. Postmenopausal.
Infectious Diseases HCV/HIV	Pola de la Torre, MD	Yolanda S. 856.968.8651	Drug Study	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.	<ol style="list-style-type: none"> 1. Male or female \geq 18 years old. 2. HIV-1 infection/HCV genotype 1 co-infection. 3. Dual NRTI backbone PLUS: Efavirenze, Raltegravir, Kaletra, Atazanavir/Ritonavir, or Darunavir/Ritonavir. 4. HIV-1 RNA < 50 copies/mL.
Infectious Diseases HIV/Tuberculosis	Pola de la Torre, MD	Cindy B. 856.968.7008	Drug Study	Ultra-short-course Rifapentine/Isoniazid for the prevention of active tuberculosis in HIV-infected individuals with latent tuberculosis infection.	<ol style="list-style-type: none"> 1. Men and women age \geq 13 years. 2. HIV-1 infection. 3. TST reactivity \geq 5 mm, or positive interferon gamma release assay (IGRA). 4. Never been treated for active or latent tuberculosis.
Infectious Diseases HIV	Rose Kim, MD	Yolanda S. 856.968.8651	Drug Study	Exploratory randomized trial to determine the bone, immunologic, virologic, and neurocognitive effects of a novel maraviroc-containing antiretroviral regimen in treatment naïve patients infected with R5-Tropic HIV-1.	<ol style="list-style-type: none"> 1. Male or female \geq 18 years old. 2. HIV-1 infection. 3. R-5 only tropism. 4. Antiretroviral drug naïve.

Study Area	Principal Investigator (PI)	Contact Info	Study Type	Study Description	Main Inclusion Criteria
Infectious Diseases/ Hematology/ Oncology	Annette Reboli, MD	Mary P. 856.757.9783	Vaccine Study	This trial evaluates to study the safety and efficacy of a herpes zoster vaccine in adults with solid tumor or hematologic malignancy.	<ol style="list-style-type: none"> >18 yrs of age receiving cytotoxic or immuno-suppressive chemotherapy or > 50 yrs. of age with hematologic malignancy, not in remission, regardless chemotherapy status. History of varicella, antibodies to VZV, or has lived in a country with endemic VZV.
Neurology TIA or minor stroke	Thomas Mirsen, MD	Patricia N. 856.968.7269 Christine B. 856.968.7222	Drug Study	This study evaluates the safety and efficacy of a drug therapy for prevention of reoccurring ischemic event.	<ol style="list-style-type: none"> Males or females over 18 years of age. High risk TIA, or, minor ischemic stroke.
Neurology Epilepsy	Melissa Carran, MD	Christine B. 856.968.7222	Drug Study	This study evaluates the safety and efficacy of drug therapy added to pre-existing antiepileptic medications for seizure control.	<ol style="list-style-type: none"> Males or females over 18 years of age. Uncontrolled partial-onset seizures. Patients on Keppra and an additional sodium channel blocking antiepileptic medication.
Trauma Surgery Acute Spinal Cord Injury	Ju-Lin Wang, MD	Lisa C-W. 856.361.1324	Drug Study	This study evaluates the safety and efficacy of drug therapy injections in adults with spinal cord injury.	<ol style="list-style-type: none"> Males or Females 18 years of age and older. Non-penetrating spinal cord injury.
Trauma Surgery	Mark Seamon, MD	Lisa C-W. 856.361.1324	Device Study	This study compares the accuracy of Non-Invasive Central Venous Pressure Method to the Standard CVP Method.	<ol style="list-style-type: none"> Males or Females 18 years of age and older. Central Venous Line placed per standard of care.
Trauma Surgery Damage Control/ Open Abdomen Surgery	Raymond Green, DO	Lisa C-W. 856.361.1324	Device Study	This study evaluates wound and adhesion characteristics in trauma damage control.	<ol style="list-style-type: none"> Males or Females 18 years of age and older. Clinical diagnosis of open abdomen due to traumatic injury for more than two surgeries.
Vascular Surgery Critical Limb Ischemia	James Alexander, MD	Jonelle O. 856.342.2150	Device Study	This study evaluates the safety and effectiveness of nucleated cells from bone marrow aspirate concentrate (BMAC) for treating lower limbs of patients with critical limb ischemia (CLI) due to peripheral arterial occlusive disease (PAOD).	<ol style="list-style-type: none"> Must have Peripheral Arterial Occlusive Disease (PAOD) with clinical Rutherford Category. Age > 18 years and ability to understand the planned treatment.
Vascular Surgery Aortic Dissection	Francis Caputo, MD	Jonelle O. 856.342.2150	Device Study	This study evaluates the safety and efficacy of an endovascular graft in the treatment of aortic dissection.	<ol style="list-style-type: none"> Age > 18 years. Must have a type B dissection of the aorta.
Vascular Surgery Carotid Artery Stenosis	Jeffrey Carpenter, MD	Jonelle O. 856-342-2150	Device Study	This study evaluates the clinical outcomes of an embolic filter in the treatment of carotid artery stenosis.	<ol style="list-style-type: none"> Age > 18 years. Must be receiving a stent for carotid artery stenosis.



For more information about clinical trials at Cooper, please call: Barbara C. at 856.342.3043

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