Ongoing Clinical Protocols at Ochsner

At any given time, between 600 and 800 active clinical trials are taking place at Ochsner Clinic and Ochsner Foundation Hospital. A selected few are listed here. If you have patients meeting the listed criteria for a given trial, please call the contact numbers for more information on enrollment. For more information about Ochsner's research programs, please call Ochsner Research Administration at 504 842-3265.

Abdominal Aortic Aneurysms

Sponsor: Cook, Inc
Contact: W. Charles Sternbergh, III, MD 504 842-4053
Glen Carter, RT(R)(CV) 504 842-2119

Title:
Endovascular treatment of abdominal aortic aneurysms with the Zenith device.

Study Design:
A prospective multicenter study of endovascular treatment of Abdominal Aortic Aneurysms (AAA). This endograft (Zenith) has a modular trifucated design, which allows treatment of AAA not possible with currently commercially available devices.

Inclusion Criteria:
- AAA >4 cm (usually $\geq$ 5 cm), or rapidly expanding
- Aortic neck diameter $\leq$ 28 mm, length $\geq$ 15 mm
- Iliac diameter between 7-20 mm

Exclusion Criteria:
- Aortic neck angulation > 60 degrees
- Excessive iliac artery tortuosity
- Inability to keep follow-up visits

Chronic Hepatitis B

Sponsor: Gilead Sciences
Contact: Robert Perrillo, MD 504 842-4893
Cheryl Denham, RN 504 842-4895

Title:
Randomized, open label multicenter study of a 10 mg daily dose of adefovir dipivoxil in combination with alpha interferon.

Adefovir has been proven effective against wild type and lamivudine resistant HBV.

Inclusion Criteria:
Chronic hepatitis B; Treatment näive; HBeAg (+); HBV DNA (+)

Chronic Hepatitis B

Sponsor: Gilead Sciences
Contact: Robert Perrillo, MD 504 842-4893
Cheryl Denham, RN 504 842-4895

Title:
Randomized, stratified double-blind multicenter study of the safety and efficacy of 52 weeks treatment with adefovir dipivoxil and lamivudine for patients with chronic hepatitis B who have developed hepatitis B virus variants and evidence of reduced therapeutic response to lamivudine.

Inclusion Criteria:
Chronic hepatitis B patients who are lamivudine resistant; HBeAg (+); HBV DNA (+)

This study enrolls 2 populations:
- Population 1: Clinically stable patients with compensated chronic hepatitis B
- Population 2: Patients with decompensated cirrhosis

Chemotherapy-Induced Fever & Neutropenia

Sponsor: Pediatric Oncology Group
Contact: Rafael S. Ducos, MD 504 842-5230
Marshall S. Schorin, MD

Title:
POG AS973: Randomized comparison between antibiotics alone and antibiotics plus granulocyte-colony-stimulating factor (G-CSF) in pediatric patients with chemotherapy-induced febrile neutropenia.

Study Design:
A prospective, randomized, multicenter study. Children with chemotherapy-induced fever and neutropenia will be randomly assigned to receive G-CSF or no G-CSF with standard empiric antibiotic therapy. Endpoints will be time to resolution of neutropenia and fever and length of hospitalization.

Inclusion Criteria:
Children 1-18 years of age on chemotherapy who present with fever (temperature > 38.3° C) and neutropenia (Absolute Neutrophil Count <500/μl).

Exclusion Criteria:
Children with acute myelogenous leukemia or myelodysplastic syndrome.

Claudication / Critical Leg Ischemia

Sponsor: Dupont Pharmaceuticals
Contact: Samuel R. Money, MD
W. Charles Sternbergh, III, MD
Frances J. Kazmier, MD
John C. Bowen, MD
Becky Himel, RN, 504 842-4070
Research Study Coordinator

Title:
Placebo controlled study to evaluate roxifiban (GP IIb/IIIa inhibitor) in the prevention of ischemic events in subjects with moderate to severe peripheral arterial disease. (Also offers claudication substudy)

Study Design:
Multicenter study that involves treating and following patients for a minimum of 1.5 years. All subjects will receive 81mg daily of ASA with either Roxifiban or placebo.

Inclusion Criteria:
- Stable moderate to severe PAD with a current ABI $\leq$ 0.60 or TBI $\leq$ 0.40 in one leg, or a previous revascularization or amputation for an ABI $\leq$ 0.60 or TBI $\leq$ 0.40 (with chart documentation).

Exclusion Criteria:
- At increased risk of bleeding as evidenced by a platelet disorder, history of or current thrombocytopenia, GI bleed within last year, peptic ulcer within last 6 months, current warfarin use or need for anticoagulant therapy, use of plavix or LMWH
- Intolerance of ASA

Deep Venous Thrombosis

Sponsor: Astra-Zeneca Pharmaceuticals
Contact: Samuel R. Money, MD
Steven B. Deitelzweig, MD
Becky Himel, RN, 504 842-4070
Research Study Coordinator

Title:
A double-blind study comparing the oral thrombin inhibitor H 376/95 versus enoxaparin and warfarin in patients with symptomatic dots with or without pulmonary embolism.

Inclusion Criteria:
- Acute symptomatic objectively confirmed lower extremity DVT with or without PE, with onset of signs or symptoms within the previous two weeks prior to enrollment.
- A planned treatment for at least 6 months at a target therapeutic INR of 2.0-3.0.

Exclusion Criteria
- Conditions associated with increased risk of bleeding
- Hemodynamic instability for patients with a PE
- Vena cava filters
- Renal insufficiency with a creatinine clearance < 30ml/min
- Liver disease

Diabetes (Type 2)

Sponsor: Pfizer
Contact: Allen Burshell 504 842-4023
Marilyn Carleton 504 842-2811

Title:
Efficacy and safety of inhaled human insulin therapy in subjects with type 2 diabetes mellitus not optimally controlled with diet and exercise: a 3-month, outpatient, parallel comparative trial.

Ochsner Clinic is the only site in the area currently conducting inhaled insulin studies using experimental powdered form insulin with a device similar to an asthma inhaler for treating type 2 diabetes. Subjects who successfully complete this 3-month trial will be eligible to receive inhaled insulin treatment in a long-term, open-label trial.

Inclusion Criteria:
- Diagnosed type 2 (adult onset) diabetes at least 2 months
- On diet & exercise only as diabetic treatment
- Age 35-80
- Nonsmoker for at least 6 months
- Willing to perform blood glucose testing at home

Exclusion Criteria:
- Respiratory disease, major organ system disease, or cancer within past 5 years
- Use of glucocorticoids
- Body Mass Index >40

A home glucose meter & supplies are supplied during the study period.

Hypothermia for Neuroprotection Following Cardiac Arrest

Sponsor: Alsius Corporation
Contact: Robert A. Felberg, MD 504 842-3980
Aura Cole 504 842-398

Title:
A prospective multicenter pilot study to evaluate the feasibility and safety of the Coolguard System with the ICY catheter following cardiac arrest.

Objective:
At present, no treatment exists for the brain damage that occurs following global anoxia. This pilot trial addresses the safety and feasibility of moderate induced hypothermia (32.5° C) for neuroprotection following cardiac arrest. The ICY catheter is inserted into the femoral vein and is capable of inducing and maintaining hypothermia.

Inclusion Criteria:
- Documented cardiac arrest
- Return of spontaneous circulation with 60 minutes of Advanced Cardiac Life Saving
- Enrollment within 90 minutes of Advanced Cardiac Life Saving
- Comatose upon presentation

Exclusion Criteria:
- Hemodynamically unstable
- Known sepsis
- Known bleeding diathesis

Patients will have access to the ICY catheter free of charge. Follow-up occurs at 30 days after discharge.

Ischemic Wounds

Sponsor: Connetics Corporation
Contact: Samuel R. Money, MD
W. Charles Sternbergh, III, MD
Frances J. Kazmier, MD
John C. Bowen, MD
Becky Himel, RN,
Research Study Coordinator 504 842-4070

Title:
Study of recombinant human relaxin therapy in patients with peripheral arterial disease.

Inclusion Criteria:
Subjects with peripheral arterial disease who have recently undergone surgical revascularization of a lower extremity and who have at least one of the following:
- An unhealed ischemic wound in the same lower extremity
- An unhealed operative wound
- An unhealed ischemic wound or operative wound and neurotrophic or venous stasis wound(s)

Exclusion Criteria:
- Subjects with proliferative diabetic retinopathy
- Diabetics with macular edema, macular degeneration or cataracts
- History of GI bleeding or peptic ulcer in the last 6 months
- Subjects needing chronic dialysis

Liver Transplantation

Sponsor: Glaxo-Wellcome
Contact: Robert Perrillo, MD 504 842-4893
Debbie Dick, RN 504-842-4425
Cheryl Denham, RN 504 842-4895

Title:
A randomized, placebo-controlled trial of lamivudine therapy for treatment naïve patients with HBV-induced cirrhosis listed for liver transplantation as UNOS status 3.

Study Design:
Patients will be randomized to receive Epivir HBV™ or placebo. Upon reaching UNOS status 2B, patients will be given open-label Epivir HBV™.

Inclusion Criteria:
- Decompensated cirrhosis due to HBV
- UNOS status 3
- Treatment naïve
- HBV DNA negative or positive

Exclusion Criteria:
- Patients in imminent need of transplant

Liver Transplantation

Sponsor: National Institutes of Health
Contact: Robert Perrillo, MD 504 842-4893
James Eason, MD 504-842-5763
Debbie Dick, RN 504-842-4425
Cheryl Denham, RN 504 842-4895

Title:
Randomized, controlled trial of lamivudine and short-term HBIg vs. lamivudine and long-term HBIg in prevention of recurrent hepatitis B post-liver transplantation.

Study Design:
Patients will be randomized to receive either a combination of lamivudine and HBIg for 3 years or lamivudine for years plus short-term HBIg (6 months or less).

Inclusion Criteria:
Decompensated cirrhosis due to HBV
Transplant eligible

Lung Transplantation

Sponsor: SangStat Medical Corporation
Contact: Vincent Valentine, MD 504 842-4922
Jackie Fearon, RN 504 842-6118

Title:
Induction immunosuppression in lung transplantation: a randomized, prospective, double blind control trial with Thymoglobulin versus Atgam.

Study Design:
Standard lung transplant protocols are followed, but the patient is randomized to either Thymoglobulin or Atgam on a 1:1 basis. The duration of the trial is 48 months. Patients are observed for the development of bronchiolitis obliterans syndrome at 6, 12 and 24 months. They are also monitored for acute rejection episodes, infections, and CMV incidence. Need for cardiopulmonary bypass, intubation time, ICU length of stay and hospital length of stay are assessed. Cost effectiveness and quality of life evaluations are made.

Inclusion Criteria:
Patients with a diagnosis of IPF, emphysema or cystic fibrosis and who are listed for lung transplantation at our center

Exclusion Criteria:
Any other diagnosis, or anyone expected to have a heart-lung transplant

Lung Transplantation

Sponsor: Novartis Pharmaceuticals
Contact: Vincent Valentine, MD 504 842-4922
Jackie Fearon, RN 504 842-6118

Title:
A three-year randomized, multicenter, double blind, parallel group study of the safety and efficacy of RAD001 versus azathioprine as adjunctive immunosuppressive therapy to inhibit the decline of pulmonary function in stable lung transplant recipients.

Objectives:
To compare the safety and efficacy of RAD versus azathioprine in stable lung transplant recipients on a stable dose of Neoral. A true reference value for pulmonary function tests is established in the qualifying period of the study; patients are followed for 3 years. Patients will be randomized to RAD twice a day or azathioprine once a day in a blinded fashion and monitored for adverse events, infections, and onset of chronic rejection following entry to the study.

Inclusion criteria:
- Lung transplant recipients from 14-70 years of age.
- Must be 3-36 months post-transplantation.
- Must have two FEV1 values, taken 3-6 weeks apart, that are >80% of their pretrial reference value.
- Must be on a stable dose of Neoral

Exclusion criteria:
- Unable to tolerate azathioprine or cyclosporine
- Undergoing treatment for CMV, pulmonary infection, acute rejection.
- Histological evidence of BOS
- HIV positive, hepatitis C positive, hepatitis B surface antigen positive.
- Patients with a white blood cell count <4,500/mm^3 or platelets <100,000/mm^3
- Patients with systemic infection, cancer or who have received other organ transplants.

Patients are provided with free study drug and Neoral. All tests ordered for the study are paid for by the sponsor.

Lung Transplantation

Sponsor: SangStat Medical Corporation
Contact: Vincent Valentine, MD 504 842-4922
Jackie Fearon, RN 504 842-6118

Title:
A randomized, controlled study of Celsior cold storage solution for flushing and hypothermic storage of donor lungs prior to pulmonary transplantation.

Study Objective:
This study compares the safety and efficacy of Celsior to Viaspan for flushing and storing donor lungs prior to transplantation. Survival will be evaluated at Days 7 and 30 post-transplant, along with the time to successful extubation. Histological assessment of pulmonary graft by biopsy will be obtained at Day 14-21 post-transplant. Chest roentgenogram evaluations will be made for evidence of diffuse alveolar damage. Need for cardiopulmonary bypass, ECMO, or inhaled nitric oxide therapy will be assessed.

Inclusion Criteria:
- Patient is a recipient of a primary single or bilateral lung transplant from a cadaveric donor
- Must be between 16 and 65 years of age
- Must practice reliable contraception for the duration of the study

Exclusion Criteria:
- Patient has received a prior pulmonary or non-pulmonary allograft
- Planned concurrent operation, e.g. coronary artery bypass
- Ventilator dependent at the time of transplantation
- Patient has acute sepsis or cystic fibrosis with pan resistant organisms
- There is evidence of active HIV, HBV or HCV infection
- Patients with primary pulmonary hypertension
- History of malignancy
- Positive pregnancy test

Celsior is provided at no charge to the patient.

Postmenopausal Osteoporosis

Sponsor:	NPS Allelix Corporation	
Contact:	Alan Burshell, MD	504 842-4023
	Marilyn Carleton	504 842-2811
	Cindy Liebel	504 842-6721

Title:
An 18-month, double-blind, placebo-controlled, phase III trial with a 12-month interim analysis of the effect of recombinant human parathyroid hormone (ALX1-11) on fracture incidence in women with postmenopausal osteoporosis.

Primary Objective:
To evaluate the incidence of vertebral (thoracic and lumbar) fractures, either new and/or worsened, in postmenopausal osteoporotic women receiving ALX1-11 supplemented with calcium and vitamin D compared to those receiving placebo supplemented with calcium and vitamin D.

Study Design:
Postmenopausal women with osteoporosis will be a randomized in a double-blind, parallel-group fashion to ALX1-11 administered subcutaneously at 100 ug per day or placebo for 18 months. The study will involve about 9 scheduled visits to the clinic.

Inclusion/Exclusion:
- Female 55 years or older with a fracture (not caused by disease or excessive trauma and not involving face, scalp, finger and or toes) and low bone mineral density (determined by a BMD x-ray scan of bones during a scheduled study screen visit), or lower bone mineral density without fracture (levels of bone mineral density are determined by the study guidelines)
- Female 45-54 years with a fracture (not caused by disease or excessive trauma and not involving face, scalp, finger and/or toes) and low bone mineral density or lower bone mineral density without fracture
- Postmenopausal at least 1 year since last menstruation
- Willing to self-administer a daily injection or have a designated person who will give injections of the study medication
- Fairly healthy with no history of or current bone cancer, no other cancer within the past 5 years, and no significant kidney, gastrointestinal, liver, musculoskeletal, vascular, lung, or serious heart diseases or HIV
- Willing to fill out questionnaires and keep records
- Cannot have received any of the following medications at any time: PTH, flouride, strontium, phenytoin or Fosamax for 12 months or longer (some limited use of Fosamax may be acceptable) *Some medications, such as calcitonin/miacalcin, raloxifene (Evista), steroids & some others, would have to be discontinued 4 weeks before screening for the study. Those on estrogen can participate in the screening bone scans & x-rays while continuing medication, but if eligible for continuing screen for the study, would need to discontinue estrogen*
- Must be able to tolerate calcium and vitamin D supplements.

All women who complete the study will be offered the opportunity to receive additional months of study medication. All study visits, procedures, medication, and parking are provided free of charge. The first 600 patients (nationwide) will have additional blood samples taken and will have to stay longer during 4 study visits. Reimbursement to participants per additional blood sampling is $150.00 for a possible total of $600.00.

Vancomycin Resistance

Sponsor:	George A. Pankey, MD	
Contact:	George A. Pankey, MD	504 842-4005
	Patricia Schaefer, RN, CCRC	504 842-5098

Title:
Cubist Pharmaceutical Protocol DAP-RRC9804: A multicenter, open-label, non-comparative study to assess the safety and efficacy of IV Cidecin™ (daptomycin) in the treatment of subjects with infections due to gram-positive bacteria that are resistant to vancomycin, or who are otherwise refractory to or contraindicated for currently available therapy.

Inclusion Criteria:
Eligible patients must have a diagnosis of an infrection due to staphylococci, enterococci, or streptococci identified by species and/or antibiogram to be resistant to vancomycin or otherwise refractory to or contrindicated for currently available therapy. Infections that may be treated under this protocol include complicated skin and soft tissue infections, complicated urinary tract infections, comunity-acquired and nonsocomial lower respiratory infections, intra-abdominal infections, and primary or secondary bactereremia as evidenced by at least two positive blood cultures associated with clinical signs and symptoms of a systemic infection. Subjects with a diagnosis of endocarditis or osteomyelitis may also be eligible for enrollment.

Exclusion Criteria:
Ineligible patients are subjects with any form of hemodialysis or peritoneal dialysis, refractory shock, hypotension or oliguria, creatinine clearence <30 mL/min or unstable renal function; subjects with elevated CPK at entry, known meningitis or empyema without drainage; HIV-infected subjects with CD_4 counts $\leq$100 cell/mm^3 or life expectancy $\leq$72 hours.