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.

Breast Cancer Prevention

Sponsor: National Cancer Institute
Investigator: Carl Kardinal, MD 504 842-3708

Title:
Study of tamoxifen and roloxifene (STAR) for the prevention of breast cancer.

Study Objective:
To determine whether raloxifene is more or less effective than tamoxifen in reducing the incidence of breast cancer in postmenopausal women at increased risk for the disease.

Inclusion Criteria
- Female over the age of 34
- Postmenopausal
- Must complete a Risk Assessment Form to evaluate eligibility

Exclusion Criteria
- History of invasive cancer
- Bilateral or unilateral prophylactic mastectomy
- History of deep vein thrombosis, pulmonary embolus, cerebrovascular accident, or transient ischemic attack
- Uncontrolled high blood pressure or diabetes

Chronic Renal Insufficiency

Sponsor: Amgen, Inc.
Contact: Jill Lindberg, MD
Melissa Palmer, 504 842-6526
Research Study Coordinator

Title:
Pilot study on the impact of anemia correction on left ventricular hypertrophy (LVH) in subjects with chronic renal insufficiency (CRI) without symptomatic heart disease treated with novel erythrpoiesis-stimulating protein.

Objectives:
To assess the safety of chronic NESP therapy in subjects with CRI. The primary objective of this multicenter, open-label, single-arm, phase II study is to determine the impact of anemia correction to a target hemoglobin of 13.0 + 1.0 g/dL on left ventricular mass index (LVMI) in subjects with CRI treated with NESP. Secondary objective is to determine the impact of anemia correction to a target hemoglobin of 13.0 + 1.0 g/dL on left ventricular end diastolic diameter (LVEDD) in subjects with CRI treated with NESP.

Inclusion Criteria:
- CRI patients between 18 and 65 years old not expected to initiate dialysis for 36 weeks after the planned first dose of study drug
- Documented LVH by EKG (confirmed at screening)
- Creatinine clearance <40 mL/min
- Mean hemoglobin <10 g/dL on two consecutive occasions
- t-sat 20%-50%
- Normal serum vitamin B12 and folate levels

Exclusion Criteria:
- Uncontrolled hypertension
- Documented ischemic heart disease, congestive heart failure, or systemic hematologic disease, or known positive HIV antibody or hepatitis B surface antigen
- r-HuEPO therapy within 12 weeks before informed consent
- Clinical evidence of severe hyperparathyroidism, current systemic infection, or active inflammatory disease
- ALT or AST more than double the upper limit of normal range

Hypothermia for Acute Myocardial Infarction

Sponsor:	Radiant Medical, Inc	
Contact:	J. Stephen Jenkins, MD	504 842-3786
	Dolores Street	504 842-5071

Title:
Hypothermia as an adjunctive therapy to percutaneous intervention in patients with acute myocardial infarction.

Study Design:
Multicenter, prospective, randomized feasibility study consisting of up to 40 patients at up to 10 clinical centers.

Objective:
To evaluate the safety and feasibility of induced hypothermia using the Radiant Medical SetPoint™ System as an adjunctive therapy to primary angioplasty in patients with acute myocardial infarction when compared with PTCA, with or without stenting.

Inclusion Criteria::
- At least 18 years of age eligible for PTCA
- Symptoms consistent with acute MI lasting >30 min but <6 h and unresponsive to nitroglycerin
- ST segment elevation of >1 mm in two or more contiguous leads

Exclusion Criteria:
- Previous MI (within 1 month) with thrombolytic treatment
- Cardiogenic shock in the absence of brachycardia or other correctable causes
- Known hypersensitivity to hypothermia (including Raynaud's), contrast media (that cannot be adequately pre-medicated), buspirone hydrochloride, or meperidine
- Hypersensitivity or contraindication to aspirin, heparin
- Currently taking MAO inhibtor
- History of bleeding diathesis, coagulopathy, renal insufficiency, untreated hypothyroidism, Addison's Disease, benign prostate hypertrophy or urethral stricture

Ovarian Cancer

Sponsor:	Gynecologic Oncology Group	
Contact:	Richard Kline, MD	504 842-3708
	Gary Lagasse, MSHCM	504-842-3708

Title:
GOG #0187: Phase II study of paclitaxel for ovarian stromal tumors as first-line or second-line therapy.

Objectives:
- Estimate the probability of clinical response and toxicity of paclitaxel as first-line or second-line chemotherapy in measurable disease patients with malignant tumors of the ovarian stroma
- Evaluate the value of inhibin for predicting response to therapy with paclitaxel

Inclusion Criteria:
- Histologically confirmed ovarian stromal tumor (granulosa cell, granulosa cell-theca cell, Sertoli-Leydig cell, androblastoma, gynandroblastoma, unclassified sex cord stromal, sex cord with annular tubules)
- Previously untreated disease diagnosed within 8 weeks prior to study entry or recurrent stromal tumor with no more than one prior chemotherapy regimen

Exclusion Criteria:
- GOG performance grade 3 or 4
- Prior invasive malignancy (except nonmelanoma skin cancer) with evidence of disease within the last 5 years or prior treatment that contraindicates the current protocol
- Amenable to cure by surgery

Prostate Cancer Prevention

Sponsor:	National Cancer Institute	
Investigator:	Carl Kardinal, MD	504 842-3708

Title:
SWOG S0000 Selenium and vitamin E cancer prevention (SELECT) phase III (prostate cancer prevention).

Study Objective:
To assess the effect of selenium and vitamin E alone and in combination on the incidence of prostate cancer.

Inclusion Criteria

- Male over the age of 54; African American men must be over the age of 49
- Participants must have a digital rectal examination that does not indicate prostate cancer
- Total prostate specific antigen count ≥ 4

Exclusion Criteria

- History of prostate cancer
- Currently receiving anticoagulant therapy
- History of hemorrhagic stroke

Skin Infections

Sponsor:
Contact: George Pankey, MD
Joseph Dalovisio, MD
Patricia Schaefer, RN, CCRC 504 842-4005

Study Title:
A prospective, randomized, double blind, multicenter trial assessing the safety and efficacy of sequential (intravenous/oral) BAY 12 -8039 (moxifloxacin) 400 mg every 24 hr compared to intravenous piperacillin/tazobactam 3.0/0.375 g every 6 hr followed by oral amoxicillin/clavulanic acid suspension 800 mg every 12 hr for the treatment of patients with complicated skin and skin structure infections.

Study Objective:
To compare the safety and efficacy of 2 sequential (intravenous/oral [IV/PO]) treatment regimens for the treatment of adult patients with complicated skin and skin structure infections.

Inclusion Criteria:

- Hospitalized male or female > 18
- Diagnosis of a skin or skin structure infection such as infected ischemic ulcer, diabetic foot, decubitus ulcer, major abscess, carbunculosis, postoperative surgical wound, or bite wound.
- Presence of at least 3 signs and symptoms [drainage/discharge, erythema, fluctuance, heat/localized warmth, pain/tenderness, swelling/induration, or fever]
- Appropriate specimen

Exclusion Criteria:

- Infection of prosthetic materials
- Folliculitis or furunculosis
- Infections where surgical procedure alone is definitive therapy
- Secondary infections
- Necrotizing fasciitis
- Uncomplicated skin and skin structure infections

Smoking Cessation

Sponsor: National Cancer Institute
Contact: Carl Kardinal, MD 504 842-3708

Study Title:
N99C4 Phase III trial comparing nicotine inhaler vs. bupropion vs. nicotine inhaler plus bupropion for smoking cessation efficacy and relapse prevention.

Study Objective:
To determine if various combinations of a nicotine inhaler and the drug bupropion can help people stop smoking and stay smoke free.

Inclusion Criteria:

- Males or nonpregnant females over the age of 18
- Currently smoking at least 10 cigarettes per day
- Has smoked regularly for the past 12 months

Exclusion Criteria:

- Pregnancy
- Current participation in another smoking cessation program
- History of seizure disorder or other serious head trauma
- Use of anti-epileptic medications
- Unstable angina or myocardial infarction in the past 3 months

Vulvar Cancer

Sponsor: Gynecologic Oncology Group
Contact: Richard Kline, MD 504 842-3708
Gary Lagasse, MSHCM 504-842-3708

Title:
GOG #0185: Phase III randomized study of adjuvant radiation treatment vs. radiation and chemotherapy (cisplatin) in patients with vulvar cancer and involved nodes.

Objectives:
- Assess whether the addition of concurrent chemotherapy to inguino/femoral and pelvic nodal irradiation improves recurrence-free interval and survival in patients with carcinoma of the vulva with positive inguino/femoral lymph nodes
- Assess the toxicity of concurrent chemotherapy and inguino/femoral and pelvic nodal irradiation in patients with carcinoma of the vulva with positive inguino/femoral lymph nodes

Inclusion Criteria:
- Primary histologically confirmed squamous cell carcinoma of the vulva stages I-III amenable to curative treatment with surgery, radiation, or both
- Must have one or more positive inguinal and/or femoral lymph nodes

Exclusion Criteria:
- Inoperable (fixed or ulcerating) groin nodes
- Metastatic disease
- Any prior chemotherapy or radiation therapy

Case Study Answers

from pages 235-236

Medical

1. The EKG in Figure 2 shows QT prolongation.
2. Checking the electrolytes (especially calcium, potassium, and magnesium) and correcting appropriately is the first step. One should look at all the medications the patient is receiving and discontinue any that would prolong QT interval.
3. Of the list of medications the patient is receiving, ciprofloxacin is the only one that can possibly prolong QT, since quiniolones have been reported to prolong QT interval. After ciprofloxacin was stopped, the QT interval decreased.
4. Yes. Prolonged QT interval can run in families, and some have a tendency to develop prolonged QT when exposed to certain medications.

Surgical

1. Cholangiocarcinoma or sclerosing cholangitis. Both can appear as single strictures of the common bile duct. Final pathology for the patient in this example revealed primary sclerosing cholangitis. This is an idiopathic stricturing disorder of the extra- and interhepatic biliary tree. Most often, the strictures are multiple and, despite the name, cholangitis is relatively unusual.
2. In cases of cholangiocarcinoma, the preferred treatment is local excision of the common bile duct with complete removal of the tumor with negative margins assessed intraoperatively, regional lymph node dissection, and, as was in this case, Roux-en-y choledocojejunostomy. Chemotherapy containing 5-FU and radiation are appropriate adjuvant therapy. Five-year survival is only 20%-50% in surgical series but is clearly better with complete microscopic excision of tumor. There is proven medical therapy for primary sclerosing cholangitis. Ursodeoycholic acid has been used to reduce cholestasis, and systemically delivered antibiotics can be necessary for episodes of cholangitis. Liver transplantation is often the only option for long-term survival.