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

CMV Prevention in Transplants

Sponsor: Roche Global Development
Contact: Sandra Kemmerly, MD 504 842-4005

Title:
A randomized, double-blind, double-dummy, active-comparator-controlled, multicenter study of the efficacy and safety of valganciclovir (Ro 107-9070) vs. oral ganciclovir for prevention of cytomegalovirus disease in high-risk heart, liver, and kidney allograft recipients (Protocol PV16000).

Inclusion Criteria:
- Has received first heart, liver, kidney, or kidney-pancreas allograft
- Seronegative for CMV pretransplant and has received an allograft from a CMV-seropositive donor
- Adequate hematological and renal function
- Able to tolerate oral medication within 10 days post-transplantation

Exclusion Criteria:
- History of CMV infection
- Has received anti-CMV therapy in the past 30 days
- Allergic adverse reaction to acyclovir, ganciclovir, or valacyclovir

Diabetes (Type 2)

Sponsor: Pfizer
Contact: 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.

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.

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.

Idiopathic Pulmonary Fibrosis and Lung Allograft Rejection

Sponsor: National Institutes of Health
Contact: Vincent Valentine, MD 504 842-4922
Jackie Fearon, RN 504 842-6118

Title:
Analyses of T-Cell Receptor Repertoires in Pulmonary Fibrosis and Lung Allograft Rejection.

Study Design:
All patients with pulmonary fibrosis will be evaluated by the collection of an extra tube of blood during their routine clinic evaluation. Pre and post lung transplant recipients will be evaluated one time pre transplant, and then every 3 months post transplant by the collection of an extra tube of blood at their clinic visits. This blood will then be examined for lymphocyte proliferations and their relationship to pulmonary fibrosis, or to the development of rejection in lung transplant patients. We hope to develop a blood test that will identify rejection before it is too late to treat it effectively, and to learn more about the process of pulmonary fibrosis in this particular patient population. This study will hopefully lead to improved outcomes in both populations.

Inclusion criteria:
- All lung transplant recipients who consent will be included in the study
- All pulmonary fibrosis patients evaluated at Ochsner will be included in the study when consented

Exclusion Criteria:
Those who are unwilling to give consent

Lung Cancer (Small-Cell)

Sponsor: Astra-Zeneca
Contact: John Cole, MD 504 842-6062
Carol Marques, RN, BSN
Alicia Cole, RN

Title:
Protocol 0473il/0004: A Phase II Open, Multicenter Trial To Assess The Activity And Tolerability Of ZD0473 Given Intravenously As Second-Line Therapy To Patients With Small Cell Lung Cancer Who Have Failed One Prior Platinum Based Chemotherapy Regimen.

ZD 0473 is an agent developed to overcome platinum resistance mechanisms.

Inclusion Criteria:
- Histological or cytological diagnosis of small cell lung cancer
- Progressive or relapsing disease having received a first-line platinum based chemotherapy
- Measurable disease
- Life expectancy greater than 2 weeks
- Performance status of 0-2

Exclusion Criteria:
- Systemic anti-cancer therapy within in the past 2 weeks
- Extensive radiotherapy
- Intracerebral metastases requiring corticosteroids or that is symptomatic design

Treatment Plan:
Patients will receive 6 courses of IV ZD0473 day 1 of a 21 day cycle. Patients with stable disease or who show a response may continue to receive additional ZD0473.

Lung Cancer (Non-Small-Cell)

Sponsor: Astra-Zeneca
Contact: John Cole, MD 504 842-6062
Carol Marques, RN, BSN
Alicia Cole, RN

Title:
Protocol 1839il/0014: A Randomized, Double Blind, Phase III Comparative Trial Of 2 Doses Of ZD1839 (Iressa^{tm}) In Combination With Gemcitabine And Cisplatin Versus Placebo In Combination With Gemcitabine And Cisplatin In Chemotherapy-Naive Patients With Advanced (Stage III Or IV) Non-Small Cell Lung Cancer.

Inclusion Criteria:
- Locally advanced stage III or stage IV non-small cell lung cancer
- Chemotherapy näive
- Performance status 0-2

Exclusion Criteria:
- Untreated brain metastases
- Less than 4 weeks since prior radiotherapy
- Grade II or greater preexisting motor or sensory neurotoxicity
- Prior systemic chemotherapy or anti-tumor therapy
- Signs or symptoms of keratoconjunctiva sicca

Treatment Plan:
All patients will receive Gemcitabine, 1000 mg/m^2 IV days 1, 8, and 15 and Cisplatin day 1 only to be repeated in cycles of 4 weeks for a total of 6 cycles. Patients will be randomized to receive one of two doses of ZD1839 or matching placebo tablets taken daily from day one. All patients will complete diary cards and quality of life questionnaires.

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 approximately 230 stable lung transplant recipients. Participants should be on a stable dose of Neoral. A true reference value for their pulmonary function tests is established in the qualifying period of the study, and then patients are followed for 3 years. RAD will be administered twice at day and azathioprine once a day. Patients will be randomized to one of these study medications in a blinded fashion. They are 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.

Male Pattern Hair Loss

Sponsor: Merck and Co.
Contact: Aura Cole 504 842-4744

Title:
A double-blind, placebo-controlled multicenter study to determine the effect of finasteride in men with advanced male pattern hair loss.

Study Design: 2-year study to determine the effect of 1 mg of finasteride on advanced male pattern hair loss.

Inclusion Criteria:
- Healthy male 18-41 years of age
- Advanced hair loss (extensive frontal or overall)
- Willing to maintain the same hair style and use same hair products for length of study

Exclusion Criteria:
- History of previous treatment with any other investigational drug(s) 3 months prior to beginning study
- History of treatment with (finasteride) Proscar or Propecia, or any other 5-alpha reductase inhibitors (i.e. saw palmetto)
- Scalp hair loss due to reasons other than androgenic alopecia

Prostate Cancer

Sponsor: Barr Laboratories, Inc.
Contact: Harold A. Fuselier, MD 504 842-4083

Title:
A phase III, randomized, multicenter, placebo-controlled, double blind clinical trial to study the efficacy and safety of CyPat® cyproterone acetate for the treatment of hot flashes following surgical or chemical castration of prostate cancer patients and its impact on the quality of life in these patients.

Inclusion Criteria:
>18 years of age; bilateral orchiectomy or using an LHRH agonist; bothersome hot flashes (defined as 3-4 moderate to severe per day or 30 per week) present for at least 1 month prior to study entry; ECOG score between 0-1; life expectancy >12 months

Exclusion Criteria:
Any of the following therapies require a 4-week washout: antineoplastic/cytotoxic agents, estrogens, antiandrogens, progestational agents, corticosteroids, clonidine, monoamine oxidase inhibitors; uncontrolled diabetes mellitus; known cardiovascular risks; thromboembolic disease; hepatic and/or renal dysfunction; other malignancy in the last 5 years

All office visits, laboratory tests, study medication, and parking fees are provided at no charge to patients.

Pediatric Immunizations

Sponsor: Aventis Pasteur, Inc
Contact: Dawn Sokol, MD 504 842-3900
Maria Martinez 504 883-3356

Title:
Safety and immunogenicity of Pentacel™ when co-administered with other recommended vaccines at 2, 4, 6, and 15 months of age.

Study Design:
Subjects receive Pentacel™ and Prevnar® at 2, 4, and 6 months in addition to Recombivax HB® depending on whether they received their first immunization at birth. At 12 months of age, patients are randomized to four dosage schedules of Pentacel™, MMR®, Varivax®, and Prevnar®.

Inclusion Criteria:
Well-term babies that have received one or NONE of the hepatitis B vaccinations to date.

Recipient receives all vaccines free of charge, all visits involving the vaccine study free of charges and $100 for completing the study.

Information for Authors

The Ochsner Journal is pleased to receive manuscripts presenting practically applicable, scientific information relevant to practicing primary care physicians. All submitted manuscripts are subject to peer review by the editorial board and other experts. The final decision on publication is made by the editor-in-chief and/or the issue editor. We are currently accepting submissions for the following issues:

April 2001, open call for papers. Deadline: November 6, 2000.

July 2001, *Diabetes*. This issue will summarize current developments in diabetes treatment and all facets of diabetes practice management. Deadline: February 5, 2001.

The Ochsner Journal intends to provide practical and applicable, scientific information on topics of great medical and societal relevance to practicing primary care physicians and physicians in training and welcomes submissions in accordance with these guidelines. The Journal accepts manuscripts that adhere to the International Committee of Medical Journal Editors Uniform Requirements for Manuscripts Submitted to Biomedical Journals, available online at www.apconline.org/journals/resource/unifreqr.htm. Address all correspondence to *The Ochsner Journal*, 1514 Jefferson Highway, New Orleans, LA 70121. The editorial offices can be reached at 504 842-6096, fax 504 842-2013, or by email at ocjournal@ochsner.org.

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The Title Page should carry: the title of the manuscript, the full name of each author and/or contributor listed in descending order of magnitude of contribution, including their academic degree(s) (only the names of those who have contributed materially to the preparation of the manuscript should be included), a 1- to 2-sentence biographical description of the author(s) (including specialty, practice location, academic appointments, primary hospital affiliation, or other credits), the date of original composition, 5 to 10 keywords for indexing purposes, and identification of sources of financial support including a declaration of any affiliations with any proprietary interests involved in the subject of the manuscript.

The Abstract should consist of no more than 250 words, be factual and informative rather than descriptive, intelligible on its own, contain abbreviations only when absolutely necessary, and be devoid of references. The abstract reports only what appears in the manuscript and contains a brief statement of the manuscript's purpose, the approach used, the material studied, and the results obtained.

References should be on separate pages immediately following the text and limited to a reasonable number. Please supply photocopies of all references. References will be critically examined at the time of review and photocopies of all sources are extremely important. All references must be cited in the text and should be arranged in order of citation. Personal communications and unpublished data should not be included in the references, but should be incorporated in the text. The following form should be followed:

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References to Books: Author(s). Title, edition number. Place of publication: Publisher, year. inclusive page numbers.

Illustrations must be submitted in photo-ready hard copies or electronic copies of at least 600dpi. All illustrations must be referred to in the body of the text. Patients in photographic material must be unrecognizable unless specific written consent is obtained. Figure number, title of manuscript, and name of principal author should be typed on a label and affixed to the back of each illustration. Legends should be on a separate page. When symbols, arrows, numbers, or letters are used to identify parts of the illustrations, identify and explain each one clearly in the legend.

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