About Ochsner

Minimally Invasive Aortic Aneurysm Repair Receives FDA Approval

The Ochsner medical institutions have been on the forefront in evaluating a new minimally invasive endovascular treatment for abdominal aortic aneurysms (AAAs), bulges in the wall of the aorta that can rupture and cause death (see *The Ochsner Journal*, October 1999). Traditional aneurysm treatments involve a major painful operation opening the entire abdomen to gain access to the weakened area of the blood vessel, 6-10 days in the hospital, and 4-6 weeks of convalescence. These new therapies allow physicians to utilize x-rays and catheters to thread a stented graft through the blood vessel to the weakened area through two small incisions with greatly reduced pain and decreased hospital stay (1-2 days).

The FDA gave final approval for the AneuRx endograft in October 1999. Dating back to 1995, Ochsner has been the only institution in the Gulf South involved in clinical trials of these devices. Over 90 endografts for treatment of AAAs have been placed at Ochsner, with approximately half of these in 1999 alone. Because of experience with this device, Ochsner is one of six training sites in the country for physicians learning to use the AneuRx endograft.

An important aspect of this new endovascular treatment has been the team approach employed. Ochsner's team includes vascular surgeons Drs. Money and Sternbergh and interventional radiologist Dr. Yoselevitz. "Each person has different expertise which combine to greatly benefit our patients," says Dr. Sternbergh.

For more information regarding endovascular AAA repair, contact Glen Carter, RT(R)(CV), endovascular AAA coordinator, at 504 842-2119 or 504 842-4053.

Ochsner Team Receives DNA Patent

In August, US Patent No. 5,936,079 was assigned to the Alton Ochsner Medical Foundation for the invention of a possible new way to cure cancer by researchers Julia L. Cook, PhD, and Richard N. Re, MD. The application of this new gene therapy that uses pieces of DNA called oligonucleotides could eventually hold promise in the treatment of cancer of the breast, prostate, and colon, among others.

In certain kinds of cells, the *p53* gene acts as a policeman. When a healthy cell is damaged by x-rays, viruses, or other carcinogens, the *p53* gene 'turns on' to produce p53 protein, which causes the damaged cell to self-destruct, thereby preventing it from becoming cancerous. Many human cancers are found to be lacking in p53 function. "What we are trying to do is replace p53 function using small pieces of DNA that can be put into a cell so as to act like p53," says Dr. Re.

Dr. Julia Cook: "We know that p53 can bind to specific stretches of DNA to regulate genes. We hypothesized that if we could use small pieces of DNA to create triple-stranded DNA at the p53 binding site, we might achieve a beneficial result. Everyone remembers the Watson-Crick model of DNA as a double helix. What we have done is to insert a third short string of DNA to create a triple helix at the p53 binding sites. When the triple-stranded DNA forms at those sites, it appears to act as if normal p53 protein were bound at those sites. We made a dozen different varieties of oligonucleotides with DNA-binding potential, hoping that they would interfere with cancer growth. We have been able to retard, and in some cases stop, cancer growth while not affecting healthy cells."

Radiology Replaces Major Surgery with Uterine Fibroid Embolization

At least one quarter of all women develop fibroids–benign tumors of smooth muscle that grow in different parts of the uterus and can cause annoying, painful problems such as pelvic, back, or leg pain; heavy menstrual bleeding; and painful intercourse. Fibroids are the leading cause of hysterectomies in the United States, but Ochsner is offering a new minimally invasive alternative involving a small incision, a catheter, and tiny polyvinyl particles that essentially starve and kill fibroids without major surgery.

Embolization teams an interventional radiologist with the patient's gynecologist who discusses treatment options with the patient, and, if embolization is the best route, the patient is then referred to the radiologist. During the procedure, a catheter is inserted into the groin at the femoral artery, and then manipulated to the uterine artery, which feeds the fibroid. Polyvinyl alcohol particles the size of sand grains are then released that cut blood flow to the fibroid. The procedure typically lasts 1 1/2 hours and does not require general anesthesia; patients typically spend only 1 night in the hospital. Hysterectomy requires a 2- hour surgery and 3-5 hospital days for recovery. For embolization, which is not considered major surgery, a week at home is usually sufficient for complete recovery.

Embolization's shorter recovery time, continued possibility for pregnancy, and minimal surgical invasion can treat all a patient's fibroids at one time, reducing the need for further procedures and trauma. Patients will experience some temporary, intense pain following the procedure, which is treated with medication. Ideal candidates for embolization are women 35 to 55 years of age (especially premenopausal women since fibroids shrink after menopause when estrogen production ceases, which is necessary for fibroids to grow) and women who have been treated with medical and surgical alternatives short of a hysterectomy.

Uterine embolization was first used in fibroid patients in France in 1995 as a means of decreasing the blood loss that occurs during the surgical removal of fibroids. It was discovered that after the embolization, while awaiting surgery, many patients' symptoms went away and surgery was no longer needed. The first embolization procedure performed in the United States was by the UCLA Medical Group in 1997. Approximately 2000 to 3000 patients have had this procedure worldwide. Ochsner initiated its Uterine Fibroid Embolization program in July 1999.

Not all fibroids have to be removed; many can simply exist in the uterus until they begin to cause problems. Initial fibroid treatments include anti-inflammatory agents or birth control pills. Further options include hormone therapy to shrink the fibroid, but once therapy stops the fibroid usually returns. Surgical alternatives include:

- *Myomectomy*: Surgical removal of fibroids (requires follow up surgery to remove new fibroids)
- *Hysteroscopy-Ablation*: Destroying the uterine lining and inhibiting future pregnancies
- *Hysterectomy*: Removal of the uterus
- *Uterine Embolization*: Starving the fibroid of its blood supply, thereby shrinking the mass and eliminating the problem

For more information regarding Uterine Fibroid Embolization contact the Ochsner Radiology Department at 842-3495.

Ochsner is the Consumer's Choice

In October 1999, for the fourth year in a row, Ochsner Foundation Hospital was named a National Research Corporation (NRC) annual Consumer Choice Award winner. Previously called the "Quality Leader Award," the name was changed to reflect the growing importance of consumer choice in the healthcare field. The NRC chose 126 hospitals nationwide as 1999 award winners by polling 170,000 households. Consumers selected winners based upon quality of care and hospital image. Ochsner was the only hospital in the greater New Orleans area to receive the award.

Ochsner Physician to Head Multinational Cancer Association in 2000

Richard J. Gralla, MD, Director of the Ochsner Cancer Institute and Head of Hematology/Oncology, has been elected President-elect of the Multinational Association of Supportive Care in Cancer (MASCC). Dr. Gralla will begin serving as President in March 2000. MASCC is the largest international organization to address supportive care in cancer. Supportive care refers to those aspects of medical care concerned with the physical, psychological, and spiritual issues faced by persons with cancer, their families, their communities, and their health care providers.

Dr. Gralla also headed the committee that recently compiled and published the American Society of Clinical Oncology's clinical practice guidelines for the use of antiemetics *(J Clin Oncol 1999; 17:2971-2994.)*.

Ochsner Implants Louisiana's First Pediatric Bi-Ventricular Assist Device

In August, Ochsner Pediatric Cardiac Surgeon Dr. James Davis and Transplant Surgeon Dr. Clifford Van Meter implanted Louisiana's first Pediatric Bi-Ventricular Assist Device (Bi-VAD). The device, which pumps blood in and out of the heart, is worn outside the body, resting on the chest.

"Bi-VAD is essentially an artificial heart sitting outside the body, acting as both ventricles of the heart, pumping the blood throughout the body," explains Dr. Davis. Bi-VAD also allows patients to lead a somewhat active lifestyle and regain their strength for transplant. The maximum length of time a patient has remained on the device is 515 days. "By placing a patient on Bi-VAD, we buy the body time to strengthen, and it also affords us the time to wait for a transplant to become available," said Dr. Davis.

Bi-VAD consists of two sets of tubing channeled through the heart and attached to two cannulae resting on the chest. Although this is not a new device, this was the first time it was put to pediatric use in Louisiana.

Bi-VAD and VAD, the only FDA-approved bi-ventricular and univentricular postcardiotomy support and bridge to transplant systems available in the United States, are multi-functional devices produced by Thoratec Laboratories (925 847-8600, www.thoratec.com). These devices have built in flexibility to support one or both ventricles of a failing or a recovering heart and can be used on all sizes of patients and in a variety of conditions. The VAD system can delay or defer an inevitable transplant by allowing the patient's heart to recover sufficient function, saving lives, time, and money.

Race for the Cure

In May, the 4th Annual Susan G. Komen Race for the Cure took place in New Orleans (one of 99 cities nationwide) to raise money for breast cancer research, education, screening, and treatment. Ochsner was New Orleans biggest corporate sponsor with a team of 175 registered runners and walkers. Several Ochsner physicians personally sponsored race participants. Thank you Drs. John Bolton, John Bowen, Gunner Cederbom, John Cole, George Fuhrman, Sandra Kemmerly, Robert Perrillo, and William Richardson for your support of this cause.

New Programs at the Ochsner Diabetes Institute

The Ochsner Diabetes Institute, one of the few diabetes programs in the New Orleans area recognized by the American Diabetes Association, has expanded its educational program. In addition to its 3-day education and training program, the Institute is adding four new 2- to 3-hour monthly classes on topics including nutrition, hypoglycemia, monitoring, medications, stress and social adjustment, behavior changing strategies, treatment of chronic complications, and much more. Classes are initially being offered on Mondays from 2pm to 5pm and Fridays from 8am to 11am on the 9th floor of the Ochsner Clinic. It is recommended that patients take the classes in order, but the program permits flexible scheduling to match individual lifestyles. Each class accommodates two to eight patients. Participants require a physician referral and should contact their insurance company for benefits details. [Louisiana law mandates that insurers pay for outpatient diabetes education.] For additional information from the Ochsner Diabetes Institute, call 504 842-3406.

Laparoscopic Surgery for GERD

Ochsner is now performing approximately 90 laparoscopic anti-reflux surgical procedures per year over a wide range of ages with excellent outcomes: 97.5 % of patients have had no or rare heartburn, 95% demonstrate no regurgitation, and the surgical complication rate is very low. Only one patient required a chest tube and no patients have required blood transfusions. Five percent of patients have had mild long-term dysphasia and 2.5% have had severe dysphasia following the procedure; two patients required dilation but none required surgery for dysphasia. There have been no long-term complaints of bloating, nausea, or diarrhea and no patients have died perioperatively. The average length of stay in the hospital is 2.5 days and the average length of time to return to normal activities is approximately 2 weeks.

Laparoscopic fundoplication should be reserved for patients with documented disease who, despite lifestyle modifications and appropriate medical therapy, still find their lives disrupted. These may include younger patients (less than 50 years of age) facing a lifetime of medication, patients who have symptoms despite their medications, patients who have difficulty complying with their drug regimen, and patients who prefer a single intervention to long term therapy. In every case, it is essential to obtain comprehensive diagnostic test results to ensure the proper course of action. Procedures require preoperative endoscopy, esophageal motility, and 24-hour ambulatory pH probe (when the diagnosis is in doubt).

If you would like to discuss a particular case, please contact William S. Richardson, MD, Director of Laparoscopy, Department of General Surgery, or John C. Bowen, MD, Chairman, Department of Surgery, at (504) 842-4070.

AASLD 50th Anniversary Campaign

Dr. Robert Perrillo was selected to be the General Chairperson for the American Association for the Study of Liver Diseases' (AASLD) 50th Anniversary fund raising campaign, *A New Era of Discovery and Hope*. In November, the campaign obtained 3.5 million dollars in grants and endowments for research and education in liver diseases($1,000,000 more than their goal). Alton Ochsner Medical Foundation became the first major donor this September, contributing $25,000 over 5 years in the form of an unrestricted grant.

Need Cardiology Info?

The Ochsner Heart and Vascular Institute's newsletter *Murmurs* is now available online at www.ochsner.org/cardiology. This resource, along with a 24-hour physician hotline (888 317-3717), provides a valuable resource for urgent questions, consultations, and referrals, as well as a forum for comments and suggestions.

CME Calendar

February 11-12, 2000
Heart Failure 2000:Tackling Heart Failure in the New Millennium
Le Meridien Hotel, New Orleans, Louisiana

This program for general practitioners, internists, cardiologists, surgeons, nursing personnel, pharmacists, and administrators will review emerging concepts in the medical, device-based, and surgical treatment of heart failure with a view to assisting the participant in placing all available treatment options in clinical perspective. The physician registration fee is $195. For more information (including travel arrangements and accommodations) contact Med Meetings, Inc. at (800) 293-7163 or www.medmeetings.com.

February 18-19, 2000
Sixth Annual Patrick Hanley Colorectal Surgery Symposium "Pathology, Radiology, Physiological Testing"
Brent House Hotel, Ochsner Hospital, New Orleans, Louisiana

This course is a comprehensive review of Colorectal Pathology, Radiology, and Physiological Testing for surgeons, gastroenterologists, and colorectal surgeons. Using extensive audiovisual aids, the faculty will review major and significant colorectal disease processes to strengthen the participants' knowledge for clinical practice of colorectal surgery. The course will be conducted in classroom style, and its size will be limited to maximize the educational opportunity of every participant. The registration fee is $150.00.

March 1-5, 2000
Society of Teachers of Family Medicine (STFM) Annual Conference on Families and Health "Celebrating the Family in Family Medicine: Looking Back, Looking Forward"
San Diego, California

For more information call (800) 274-2237 or email: assndfm@stfm.org.

March 30-April 2, 2000
Colorectal Surgery: Issues and Updates, Piedmont Society for Colorectal Surgeons
Caesar's Palace, Las Vegas, Nevada

This conference is targeted to General and Colorectal Surgeons and Residents, and it provides a forum for disseminating information and for encouraging open discussion between the society members and the academic surgeons. The small forum promotes the dialogue surrounding the controversial treatment and diagnostic issues. The Alton Ochsner Medical Foundation designates this educational activity for a maximum of 7 hours of Category 1 credit towards the AMA Physician's Recognition Award. The registration fee for this conference is $200.00. For registration information, please contact the Alton Ochsner Medical Foundation at (800) 778-9353 or (504) 842-3702.

April 27-29, 2000

Tenth Annual Endocrinology Update

(During the New Orleans Jazz and Heritage Festival)
Hyatt Regency Hotel, New Orleans, LA

This conference is designed for Endocrinologists, Internists, and Family Practice physicians as an update in new therapies that have been or will soon be available to physicians in many areas of endocrinology. A combination of lectures, question/answer sessions, audio visuals, handouts, and workshops are used to communicate the educational objectives. This conference is being conducted in classroom style seating. The Alton Ochsner Medical Foundation designates this educational activity for a maximum of 17 hours of Category 1 credit towards the AMA Physician's Recognition Award. The registration fee is $400.00. For registration information, please contact the Alton Ochsner Medical Foundation at (800) 778-9353 or (504) 842-3702.

April 29-30, 2000

Annual Tri-State Anesthesia Meeting

(During the New Orleans Jazz and Heritage Festival)
Hyatt Regency, New Orleans, Louisiana

This conference is both a clinical and administrative update which addresses issues pertinent to the anesthesia practice of 2000; a potpourri of disciplines will be updated including new techniques in the field of anesthesia, governmental and legislative approaches. Please telephone the Alton Ochsner Medical Foundation, Continuing Medical Education at (800) 778-9353 or (504) 842-3702.

May 3-7, 2000

Annual Meeting of the Society of Teachers of Family Medicine (STFM) "Exploring the Vision of Family Medicine: Research, Technology, and Practice"

Orlando, Florida

Further information can be obtained from Priscilla Noland at (800) 274-2237 ext4510 or email: assndfm@stfm.org.

May 12, 2000

18th Annual Dr. John C. Weed Obstetrics and Gynecology Resident Research Seminar

Brent House Hotel, Ochsner Hospital, New Orleans, LA

This conference is an opportunity for our residents to present data which they have accumulated in the areas of interest. This is coupled with presentations by a guest lecturer encompassing a broad spectrum of topics in the field of obstetrics and gynecology. This conference is intended for OB/GYN physicians, nurses and nurse practitioners. This conference is being conducted in theater style seating. There is no registration fee for this conference.

June 25-27, 2000

17th Annual Meeting of the Association for Health Services Research (AHSR)

Los Angeles, California

The date of the call for papers is November 1999, and the deadline is January 2000. For further information call (202) 223-2477 or go to the website at www.ahsr.org.

August 1-6, 2000

22nd Annual New Orleans Internal Medicine Board Review Course

Hyatt Regency, New Orleans, Louisiana

The Board Review is designed for internists as a comprehensive review of internal medicine as preparation for taking the American Board of Internal Medicine Certification and Recertification Examinations or as a review for Board-certified physicians. After participating in this educational activity, the registrant should be better able to: diagnose and treat the diseases of the adult population, implement strategies of prevention of diseases, and successfully take the board exam. This activity is co-sponsored by the Alton Ochsner Medical Foundation, Louisiana State University Medical Center, and Tulane University Medical Center. The host this year is LSUMC. For registration information, please telephone LSUMC, Continuing Medical Education at (800) 648-5272 or (504) 568-6085.

On-Going Clinical Protocols at Ochsner

Bone Metastases Other Than Breast or Prostate Cancer or Multiple Myeloma

Sponsor: Schering-Plough Research Institute
Contact: Cindy Rittenberg, RN 504 842-3708

Title:
Protocol CGP-4244603-011: A randomized, double-blind, placebo-controlled, multicenter trial to evaluate the safety and efficacy of Zoledronate (4 and 8 mg) administered intravenously as an adjuvant to anticancer therapy to patients with any cancer with bone metastases other than breast cancer, multiple myeloma, or prostate cancer.

Inclusion Criteria:
- Diagnosis of cancer other than breast, prostate, or multiple myeloma
- Objective evidence of metastatic bone disease within 6 weeks of trial entry
- No previous treatment with a biphosphonate

Study Design: Patients are randomized to receive by rapid iv infusion Zoledronate 4 mg, Zoledronate 8 mg, or placebo. Patients may receive concomitant standard anti-neoplastic radiation or cytokine colony stimulating therapy.

Breast Cancer Prevention

Sponsor: Eastern Cooperative Oncology Group
Contact: Carl G. Kardinal, MD 504 842-3708
Chris D'Arcangelo, RN 504 842-3708

Title:
Protocol E1496: Randomized phase III study in low grade lymphoma comparing cyclophosphamide/fludarabine to standard therapy followed by maintenance anti-CD20 antibody.

Inclusion Criteria:
- Stage III-IV low grade non-Hodgkin's lymphoma
- Must have at least one objective measurable disease parameter IDEC-C2B8 (Rituximab) provided

Breast Cancer Prevention

Sponsor: National Surgical Adjuvant Breast and Bowel Project
Contact: Carl G. Kardinal, MD
Kate Rodger, RN 504 842-3708

Title: Study of tamoxifen and raloxifene for the prevention of breast cancer.

Inclusion Criteria:
Postmenopausal women age 35 or older
Must be risk eligible determined by the Gail Model:
- Family history; mother, sister(s), daughter(s)
- Age
- Nulliparous
- Having a first child after age 30
- Early menarche
- History of benign breast disease requiring biopsies
- LCIS or atypical hyperplasia

Breast Cancer

Sponsor: National Surgical Adjuvant Breast and Bowel Project
Contact: Carl G. Kardinal, MD 504 842-3708
Cindy Rittenberg, RN 504 842-3708

Title:
A 3-arm randomized trial to compare adjuvant Adriamycin and cyclophosphamide followed by Taxotere; Adriamycin and Taxotere; and Adriamycin, Taxotere, and cyclophosphamide in breast cancer patients with positive axillary lymph nodes.

Inclusion Criteria:
- Tumor confined to breast and ipsilateral axilla on clinical exam (T1-3, N0-1, M0)
- At least 1 positive axillary lymph node on path exam
- Time from initial Dx to randomization < 63 days
- L VEF (MUGA or echo) > lower limit of normal

Taxotere is provided.

Liver Transplant

Sponsor: SangStat
Contact: Dr. James Eason 504 842-5763
Dr. George Loss

Title:
Randomized prospective trial using thymoglobulin induction in liver transplant recipients to eliminate steroid usage.

Inclusion Criteria:
All adult liver transplant candidates giving informed consent.

Melanoma

Sponsor: Sunbelt Melanoma Trial (Cooperative Group of Surgical Oncologists)
Contact: George Fuhrman, MD 504 842-4070
Cindy Rittenberg, RN 504 842-3708

Title:
Sunbelt Melanoma Trial (SMT): A multicenter trial of adjuvant interferon ALFA-2b for melanoma patients with early lymph node metastasis detected by lymphatic mapping and sentinel lymph node biopsy.

Inclusion Criteria:
- Patients with melanoma > 0.76 mm thick or Clark's level III invasion and clinically negative nodes
- The primary cutaneous melanoma must be on the head, neck, trunk, extremity, palm of hand, or sole of foot
- Patients must be between the ages of 18 and 70
- Patients cannot have a wide skin excision prior to randomization and treatment

Myelodysplastic Syndrome

Sponsor: Eastern Cooperative Oncology Group
Contact: Chris D'Arcangelo, RN 504 842-3708

Title:
E 1996: Phase III evaluation of EPO with or without G-CSF versus supportive therapy alone in the treatment of myelodysplastic syndromes.

Inclusion Criteria:
- Myelodysplastic syndrome RA, RA-S, or RAEB as defined by the FAB as cooperative groups
- No androgens or steroids within 2 weeks prior to starting treatment

Non-Hodgkin's Lymphoma

Sponsor: Eastern Cooperative Oncology Group
Contact: Carl G. Kardinal, MD 504 842-3708
Chris D'Arcangelo, RN 504 842-3708

Title:
Protocol E4492: Phase III trial of CHOP versus CHOP and chimeric anti-CD-20 monoclonal antibody (IDEC-C2B8) in patients 60 years or older with diffuse mixed, diffuse large cell, and immunoblastic large cell histology non-Hodgkin's lymphoma.

Inclusion Criteria:
- Intermediate or high grade non-Hodgkin's lymphoma, B-cell, positive CD20 and/or CD9
- At least one measurable disease parameter
- No prior treatment except corticosteroids
- Pretreatment IgG level greater than 500 mg/dL

IDEC-C2B8 (Rituximab) provided

Ovarian Cancer

Sponsor: Schering-Plough Research
Contact: Richard Kline, MD 504 842-3708
Cindy Rittenberg, RN 504 842-3708

Title:
Protocol C98-102: A phase II/III trial of chemotherapy alone versus chemotherapy plus SCH 58500 in newly diagnosed stage III ovarian and primary peritoneal cancer patients with ≤2 cm residual disease (0-2 cm) following surgery.

Inclusion Criteria:
- Stage III epithelial, ovarian, or primary peritoneal cancer
- Residual disease ≥ 0.5 cm and ≤ 2 cm following cytoreductive surgery
- Mutant or null p53 gene
- Serologically positive for anti-adenovirus antibodies at sc reening

Study Design: Patient is randomized to receive Taxol/Carbo plus SCH 58500 for cycles 2 through 6 of chemotherapy.

Pancreatic Cancer

Sponsor: SuperGen
Contact: Edwin A. McElroy, Jr., MD 504 842-3708
Cindy Rittenberg, RN 504 842-3708

Title:
Protocol RFS 2000-02: Phase III randomized study of RFS 2000 (9-nitro-camptothecin, RFS 2000) versus gemcitabine HCL in chemonaive pancreatic cancer patients.

Inclusion Criteria:
- KPS ≥ 50
- Chemotherapy näive

Pancreatic Cancer

Sponsor: SuperGen
Contact: Cindy Rittenberg, RN 504 842-3708

Title:
Protocol RFS 2000-09: Phase III study of RFS 2000 (9-nitrocamptothecin, 9-NC) versus most appropriate chemotherapy in refractory pancreatic cancer patients.

Inclusion Criteria:
- Patients must have failed or relapsed after receiving at least one prior chemotherapy regimen (other than gemcitabine or 5-FU as a radiation sensitizer as their only chemotherapy)

Study Design: Patients are randomized to receive oral RFS 2000 given daily x5 followed by a 2-day rest, or to the most appropriate chemotherapy available.

Pancreatic Cancer

Sponsor: SuperGen
Contact: Edwin A. McElroy, Jr., MD 504 842-3708
Cindy Rittenberg, RN 504 842-3708

Title:
Protocol RFS 2000-06: Phase III randomized study of RFS 2000 (9-nitrocamptothecin, 9-NC) versus 5-fluorouracil (5-FU) in pancreatic cancer patients that have progressive disease following gemcitabine HCL treatment.

Inclusion Criteria:
- KPS ≥ 50
- Must have received gemcitabine and have progressive disease during or following treatment
- Cannot have received any other chemotherapy except gemcitabine

Study Design: Patients will be randomized to either oral RFS 2000 given daily x5 followed by a 2-day rest, or to iv 5-FU given weekly.

Rheumatology

Sponsor: Immunex Corporation
Contact: Dr. William E. Davis 504 842-3920

Title:
Immunex protocol 16.0012 – recombinant human tumor necrosis factor receptor fusion protein (TNFR:Fc) vs. methotrexate in rheumatoid arthritis.

Inclusion Criteria:
- Active early RA as duration of disease = 3 years (36 months)
- No prior treatment with methotrexate

Exclusion Criteria:
- Intra-articular, soft tissue, or intra-muscular corticosteroid injection during 4 weeks prior to screening
- Treatment with cyclophosphamide within 6 months prior to screening
- Presence of anti-DNA antibodies at screening or history of anti-cardiolipin antibodies associated with a thrombotic event or recurrent fetal loss syndrome

Rheumatology

Sponsor: University of Connecticut Health Center
Contact: Dr. Robert Quinet 504 842-3920

Title:
The national woman arthritis study.

Inclusion Criteria:
Women 18-64 with no life-threatening illnesses: cancer, heart disease

Patient paid $100 the first year for participation – a yearly phone interview

Rheumatology

Sponsor: Merck & Co.
Contact: Dr. Leonard Serebro 504 842-3920

Title:
A double blind randomized stratified parallel group study to access the incidence of PUBs during chronic treatment with MK-0966 or Naprosyn in patients with rheumatoid arthritis: US cohort.

Inclusion Criteria:
Male or female at least 50 years old having rheumatoid arthritis and in good health

Exclusion Criteria:
Inflammatory arthritis, history of ulcer or GI bleed or inflammatory bowel disease, active hepatitis, stroke, allergic to acetaminophen or hypersensitive to aspirin, naproxen, or other NSAIDs.

Rheumatology

Sponsor: Merck & Co.
Contact: Dr. Robert Quinet 504 842-3920

Title:
A randomized multi-center study to evaluate the tolerability and effectiveness of rofecoxib (MK-0966) 25 mg q.d. vs. naproxen 500 mg b.i.d. in patients with osteoarthritis.

Inclusion Criteria:
- At least 40 years of age
- Osteoarthritis in knee, hip, or spine for >6 months
- History of therapeutic benefit in OA of the knee, hip, hand, or spine with NSAID or acetaminophen use

Exclusion Criteria:
- Diagnosed as American College of Rheumatology Functional Class 4
- Concurrent medical or arthritic disease that could confound or interfere with evaluation of efficacy including inflammatory arthritis
- History of GI malabsorption
- Allergic to naproxen, acetaminophen or hypersensitive to aspirin, ibuprofen, naproxen, or other NSAIDs

Rheumatology

Sponsor: Searle & Co.
Contact: Dr. Robert J. Quinet & Dr. Leonard Serebro 504 842-3920

Title:
Clinical protocol for a multi-center double blind parallel group study comparing the incidence of clinically significant upper gastrointestinal adverse events associated with SC-58635, 400 mg b.i.d. to that of diclofenac 75 mg b.i.d. in patients with osteoarthritis or rheumatoid arthritis, IND 48395. The Celecoxib long-term arthritis safety study (class 2).

Inclusion Criteria:
- Legal age of consent
- Documented clinical diagnosis of OA or RA of at least 3 months duration as chronic NSAID therapy

Exclusion Criteria:
- Active malignancy of any type or history of a malignancy
- Diagnosed and treated for esophageal gastric pyloric channel or duodenal ulceration within 30 days prior to the first dose
- Active GI disease
- History of gastric or duodenal surgery or any renal or hepatic dysfunction
- Abnormal screening/laboratory abnormality
- Known hypersensitivity to Cox-2 inhibitors, sulfonamides, or Diclofenac

Rheumatology

Sponsor: School of Public Health and Tropical Medicine at Tulane University Medical Center
Contact: Dr. Leonard Serebro 504 842-3920

Title:
Environmental factors in the etiology of fibromyalgia in women.

Inclusion Criteria:
Primary diagnosis fibromyalgia

Exclusion Criteria:
No other connective tissue disease

All doctor visits, lab work, x-rays, endoscopies, and medication required for any of these particular studies are no charge to the patient.