Ongoing Clinical Protocols at Ochsner

At any given time, between 600 and 800 active clinical trials are taking place at Ochsner. 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.

Carotid Endarterectomy vs. Carotid Stenting

Sponsor: Guidant Corp.
Investigator: Samuel R. Money, MD
Contact: (504) 842-4053

Title:
Carotid revascularization endarterectomy vs. stent trial (CREST).

Study Objective:
This study will contrast the relative efficacy of carotid angioplasty stenting versus carotid endartectomy in preventing stroke, myocardial infarction, and death during a 30-day periprocedural period, and stroke ipsilateral to the study artery over the follow-up period in patients with symptomatic carotid stenosis.

Inclusion Criteria:
- 18-20 years of age
- Symptomatic as evidenced by transient ischemic attack, amaurosis fugax, minor or non-disabling stroke within 180 days of randomization
- Candidate for carotid endarterectomy
- Carotid stenosis $\geq$ 50%
- Target ICA vessel diameter $\geq$ 4 mm and $\leq$ 9 mm

Exclusion Criteria:
- Pregnant
- Evolving stroke
- Active bleeding diathesis or coagulopathy
- History of major ipsilateral stroke or spontaneous intracranial hemorrhage
- Severe dementia
- Hgb < 10 g/dL, platelet count < 125,000, uncorrected INR > 1.5
- Vertebrobasilar symptoms only
- Knowledge of cardiac sources of emboli
- Myocardial infarction within 30 days
- Recent GI bleeding
- Unstable angina
- Dialysis-dependant renal failure
- Uncontrolled diabetes
- Recent neck trauma or major surgery
- Spinal immobility
- Previous carotid endarterectomy, EC-IC or subclavian bypass ipsilateral to carotid stenosis

Ultrasound Enhanced Thrombolysis

Sponsor: Genetech
Investigator: Robert A. Felberg, MD
Contact: (504) 842-6399

Title:
Combine lysis of thrombus in brain ischemia with transcranial ultrasound and systemic thrombolysis (CLOTBUST).

Study Objective:
This trial will study the effectiveness and safety of a simple, noninvasive and inexpensive method of enhancing thrombolytic therapy for ischemic stroke at centers with expert sonographers and stroke treatment teams. A major objective of this pilot phase II randomized clinical trial is to compare rates of recanalization and recovery between patients treated with standard tPA dosage vs. patients treated with tPA while continuosly monitored by 2 MHz transcranial Doppler. The data obtained through this trial will form the basis for a properly powered phase III randomized trial of ultrasound enhanced thrombolysis compared with intravenous tPA alone.

Inclusion Criteria:
- Measurable focal neurological deficit (NIHSS $\geq$ 4)
- IV tPA infusion intiated within 3 hours of symptom onset
- Diagnostic transcranial Doppler completed before tPA bolus

Exclusion Criteria:
- CT evidence of intracranial hemorrhage
- Primary intra-arterial thrombolysis
- Active internal bleeding
- Intracranial or intraspinal trauma
- Intracraial neoplasm, arteriovenous malformation, or aneurysm
- Uncontrolled hypertension
- Known bleeding diathesis

tPA and study-related Doppler studies will be at no cost to the patient.

Perfusion Augmentation by Aortic Catheter

Sponsor: CoAxia, Inc.
Investigator: Robert A. Felberg, MD
Contact: (504) 842-6399

Title:
A clinical feasibility study of perfusion augmentation in acute ischemic stroke using controlled aortic obstruction.

Study Objective:
This study will test the safety of a catheter placed in the lower aorta to temporarily limit blood flow to the legs in order to allow more blood to be directed to the brain. Animal studies have shown that increasing blood flow to the brain may reduce the amount of tissue affected by stroke.

Inclusion Criteria:
- 18-75 years of age with symptomatic, acute cerebral ischemia
- Device deployment within 12 hours of stroke onset

Exclusion Criteria:
- CT evidence of intracranial hemorrhage or transformation
- Mass effect or intracranial tumor
- Symptoms mild or resolving by time of device deployment
- Pregnant
- Known cerebral aneurysm or history of intracranial bleeding
- Intraventicular hemorrhage
- Hypertension requiring aggressive therapy and/or use of Coumadin, heparin, or thrombolytics
- Coagulopathy with INR > 1.7 or PTT > 1.5 times local control or platelet count < 100,000
- Aortic diameter ≥ 23 mm within 6 cm below midpoint of renal arteries or ≥ 27 mm within 6 cm above midpoint of renal arteries
- History or evidence of aortic aneurysm or aortic regurgitation
- History of renal failure or creatinine clearance > upper limit of normal
- End stage AIDS
- History of claudication
- Severe dementia
- History of pelvic abdominal mass likely to compress aorta
- Myocardial infarction in previous 6 months
- Chronic heart failure
- Angina
- Recent or current supraventricular or ventricular tachycardia
- Ejection fraction ≥ 40%

Catheter and study-related angiograms, echocardiography, CT, MRI and PET studies that include blood flow measurements will be at no cost to the patient.

Carotid Stent System

Sponsor: Advanced Cardiology Systems, Inc.
Investigator: Stephen Ramee, MD
Contact: (504) 842-3000

Title:
A prospective, non-randomized, multicenter, single-arm clinical trial to assess the safety and efficacy of the Acculink carotid stent with the Accunet embolic protection system in the treatment of high-risk surgical patients and non-surgical patients with lesions in the internal carotid artery. ARCHeR trial.

Study Objective:
This study will test the safety and effectiveness of the Acculink carotid stent system in the carotid artery. The primary objective is to demonstrate equivalence in combined 30-day stroke, death and myocardial infarction rate and 1-year ipsilateral stroke rate between high-risk surgical and non-surgical patients treated with Acculink and an historical control established through recent literature review.

Inclusion Criteria:
- High-risk surgical candidate ≥ 18 years of age
- Symptomatic: transient ischemic attack, amaurosis fugax, or minor/non-disabling stroke within 180 days of enrollment
- Discrete lesion located in internal carotid artery
- ≥ 50% stenosis
- Target vessel ≥ 4 mm and ≤ 9 mm

Exclusion Criteria:
- Pregnant
- Evolving stroke
- Active bleeding diathesis or coagulopathy
- History of major ipsilateral stroke
- Severe dementia
- History of spontaneous intracranial hemorrhage
- Hgb < 8 gm/dL, platelet count < 50,000, uncorrected INR > 1.5
- Heparin-associated thrombocytopenia
- Life expectancy < 2 years
- Vertebrobasilar symptoms only
- Knowledge of cardiac sources of emboli
- Recent GI bleeding
- Previous intravascular stent or graft
- Intralumnial filliing defect
- Extensive or diffuse atherosclerotic disease
- Abnormal angiographic findings

Non-routine diagnostics (repeat ultrasound, angiogram) will be at no cost to the patient.