

NCRO HIGHLIGHTS

Duke
Neuroscience

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



May 2007

The mission of the NCRO is to foster the development of a world-class neuroscience clinical trials center.

Who's Who in the NCRO

| Management | Coordination | Email: |
|--|-----------------------|--|
| Mark Stacy, Medical Director | Kate Beck 668-2278 | beck0002@mc.duke.edu |
| Ron Beauvais, Administrator | Gail Cook 684-0865 | cook0007@mc.duke.edu |
| Donna Carnes, Clinical Trials Assistant | Joanne Field 668-2842 | joanne.field@duke.edu |
| Lisa Gauger, Clinical Research Administrator | Karen Grace 668-2844 | karen.grace@duke.edu |
| JoAnn Jones, Regulatory Administrator | Debra Heydt 668-2843 | debra.heydt@duke.edu |
| Cathy O'Neill, Finance Manager | Rene Link 970-1648 | link0002@mc.duke.edu |
| Jackie Woody, Clinical Trials Assistant | Sarah Wyne 668-2837 | wyne0001@mc.duke.edu |

ACTIVE ENROLLING STUDIES

The NCRO currently supports **43** active studies. This list includes only those studies that are actively enrolling. Please help us reach our targets (column 6).

DEMENTIA STUDIES

| PI | SPONSOR | INDICATION | STUDY-ID | COORDINATOR | TARGET / # PTS ENROLLED-5/31/07 |
|--------------|-----------------|--|-------------------------------------|----------------|---------------------------------|
| BURKE, Jim | GlaxoSmithKline | Mild to Moderate AD | Rosiglitazone XR (49653/461) | Heydt 668-2843 | 15 / 12 |
| BURKE, Jim | GlaxoSmithKline | Mild to Moderate AD on Donepezil treatment | Rosiglitazone XR (REFLECT-2 102672) | Heydt 668-2843 | 15 / 0 |
| WHITE, Heidi | NIH | Mild cog. Impairment | Nicotine Tr of MCI | Cook 684-0865 | 25 / 27 |

MOVEMENT DISORDERS

| | | | | | |
|-------------|----------------------|---|-----------------------------------|-----------------|-----------------|
| SCOTT, Burt | Physician Funded | Movement disorder | Visual Documentation | N/A | No Target / 532 |
| SCOTT, Burt | Physician Funded | Movement disorder | Tetrabenazine | N/A | No Target / 79 |
| SCOTT, Burt | Boehringer Ingelheim | PD tx'd with Mirapex / other anti-PD agents | BI 248.619 Dominion | Field 668-2842 | 75-225 / 79 |
| SCOTT, Burt | EISAI | PD | E2007-A001-302 | Heydt 668-2843 | 25 / 3 |
| SCOTT, Burt | Merz Pharmaceuticals | Cervical Dystonia | MRZ 60201-0408 | Heydt 668-2843 | 6-8 / 5 |
| SCOTT, Burt | NIH/NINDS | PD – early treated | Creatine (LS-1) | Grace 668-2844 | 36 / 1 |
| STACY, Mark | Novartis | PD | Quest PD(CELC200AUS11) | Field 668-2842 | 10 / 1 |
| STACY, Mark | Ceregene | Idiopathic PD | Cere-120-02 | Gauger 668-1538 | 6-8 / 4 |
| STACY, Mark | GE Healthcare | Normal Human volunteers | TR0107 (99mTc-NC100697 Injection) | Field 668-2842 | 15 / 3 |
| STACY, Mark | Merz Pharmaceuticals | Blepharospasm | MRZ 60201-0433 | Heydt 668-2843 | 10 / 0 |

MULTIPLE SCLEROSIS

| | | | | | |
|-------------|--------------------|--|-----------------------|---------------|-------|
| SKEEN, Mark | Opexa Therapeutics | Clin Isolated Syndrome or Relapsing Remitting MS | Tovaxin/TERMS 2005-00 | Wyne 668-2837 | 5 / 0 |
|-------------|--------------------|--|-----------------------|---------------|-------|

NEUROMUSCULAR

| | | | | | |
|---------------|----------------------|----------------------------------|---------------------------|----------------|-----------|
| BEDLACK, Rick | NIH, MDA, ALS Assoc. | ALS-motor neuron diseases | DNA Banking Repository | Heydt 668-2843 | 120 / 104 |
| BEDLACK, Rick | UCB Pharma | Motor neuron disease | Levetiracetam | Heydt 668-2843 | 20 / 21 |
| BEDLACK, Rick | Physician Funded | ALS, Myopathy & Healthy Controls | HDAC Expression in Muscle | N/A | 12 / 0 |

VASCULAR

| | | | | | |
|------------------|------------------|------------------------|----------------------------|---------------------|------------|
| GOLDSTEIN, Larry | AGA Med Corp | Cryptogenic stroke | RESPECT | Link 970-1648 | 40 / 24 |
| GRAFFAGNINO, C | CoAxia, Inc. | Acute ischemic stroke | SENTIS-CD-0125 | Stoner 668-5275 | 10 / 0 |
| LASKOWITZ, Danny | Physician funded | Biomarker-brain injury | Stroke Panel of Biomarkers | E. Bennett 668-1429 | 1000 / 786 |
| LASKOWITZ, Danny | NINDS | Acute ischemic stroke | Human Albumin | E. Bennett 668-1429 | 25 / 3 |

GERIATRICS

| | | | | | |
|--------------|-------|--|----------|---------------|--------|
| WHITE, Heidi | Amgen | Observational-Anemia & Chronic Kidney Ds | 20050239 | Cook 684-0865 | 25 / 7 |
|--------------|-------|--|----------|---------------|--------|

NON-NCRO TRIALS

| | | | | | |
|------------------|--------------------------------|-----------------------------------|--|-------------------|--------|
| BROWNDYKE, Jeff | Ortho-McNeil Neurologics, Inc. | Mild AD | GAL-EMR-4026 | Wyne 668-2837 | 36 / 2 |
| BUSHNELL, Cheryl | Hazel K. Goddess Fund | Pregnant women with pre-eclampsia | Transcranial Doppler & Biomarker Pilot | CBusnell 684-5650 | 50 / 4 |
| GRAFFAGNINO, C | NIH / Wash Univ | Carotid occlusion - COSS | Surgery vs stan med care | Stoner 668-5275 | 30 / 4 |

******STUDY SPOTLIGHT******

New Approved Studies Ready for Recruitment!!
Please see further details below – Thank you for your Support!

R. Bedlack (PI) – HDAC Expression in Muscle – ALS, Myopathy & Healthy Controls**“HDAC4 Expression in Muscle from ALS Patients, Myopathy Patients and Healthy Controls”**

The purpose of this study is to determine the amount of histone deacetylase 4 (HDAC4) expressed in deltoid muscle biopsies from 3 healthy patients, 3 patients with deltoid weakness from primary muscle disease, 3 patients with amyotrophic lateral sclerosis (ALS) who have strong deltoids and 3 patients with ALS who have severe deltoid weakness. Animal research performed at Duke suggests that HDAC4 might play an important role in ALS pathophysiology and that the level of its expression in muscle might be useful as a diagnostic and evaluative outcome measure. Subjects will have a single study visit during which they will have a needle punch biopsy on one of their deltoid muscles. The tissue will be sent to the lab where expression of HDAC4 will be quantified. The study design will allow determination of whether HDAC4 expression occurs early in the course of disease (before significant atrophy or weakness) or later and also whether the increase in HDAC4 is specific for denervation-induced muscle atrophy or a more global marker of atrophy that is present even in primary myopathic states. You may contact Dr. Rick Bedlack (668-2839) for more information on this study.

M. Stacy (PI) – GE Healthcare (TRO 107)**“A Multicenter, Phase I, Open-Label, Non-Randomized Study to Determine the Striatal Uptake of ^{99m}Tc-NC100697 Injection in Normal Human Volunteers Using Dual-Headed SPECT Cameras”**

The primary objective of this study is to estimate the variability in striatal binding ratio (SBR) resulting from inter-camera differences in count sensitivity and resolution using dual-headed single-photon emission computed tomography (SPECT) cameras. The availability of a definitive diagnostic test would help provide an earlier diagnosis of Parkinsonian Syndromes (PS). PS are medical conditions characterized by combinations of motor-related neurologic signs: rest tremor, bradykinesia, rigidity, loss of postural reflexes, flexed posture, and the freezing phenomenon. PS are also sometimes referred to as parkinsonism. Diagnostic accuracy is a function of both disease stage (diagnosis is more difficult the earlier the stage) and examiner expertise. It is hoped the medical need may be met by ^{99m}Tc-NC100697 Injection which is being developed as a diagnostic radiopharmaceutical for use during single-photon emission computed tomography (SPECT) imaging to help detect or exclude striatal dopaminergic deficits. We anticipate recruiting 15 healthy volunteers aged ≥ 41 years of age (from 5 age-related cohorts) here at Duke. You may contact Dr. Mark Stacy or Joanne Field (668-2842) for more information on this study.

M. Stacy (PI) – Merz Pharmaceuticals (MRZ 60201-0433)**“Prospective, Double-Blind, Placebo-Controlled, Randomized, Multi-Center Trial with an Open-Label Extension Period to Investigate the Efficacy and Safety of NT 201 in the Treatment of Blepharospasm”**

The primary objective of the main period of this study is to investigate the safety and efficacy of NT 201 compared with placebo in the treatment of benign essential blepharospasm. The open-label extension period will consist of a 48-week treatment period and a safety observation period of up to 20 weeks after the last injection of NT 201. Merz Pharmaceuticals has developed NT 201 to reduce the immunogenic potential associated with existing Botulinum toxin Type A (BTX-A) preparations. NT 201 is a freeze-dried formulation of Botulinum Neurotoxin (BoNT)/A and is free of complexing proteins. No immunogenicity has been detected in animal models using NT 201. The highly purified nature of NT 201 is thought to represent a clinical advance compared with existing preparations of BTX-A containing hemagglutinins. The main period of the study will last at least 7 and up to 21 weeks. The extension period will consist of a treatment period up to 48 weeks and a safety observation period up to 20 weeks after the last injection. We anticipate recruiting 10 subjects here at Duke. You may contact Dr. Mark Stacy or Deb Heydt (668-2843) for more information on this study.

Duke University School of Medicine
Clinical Research Support Office (CRSO)
LUNCH AND LEARN SERIES
2007 Schedule
CHANGES NOTED BELOW

The Clinical Research Support Office (CRSO) is now in charge of the Lunch/Learn Series. More information will follow as the schedule is updated.

Lunch & Learn Series

All Lunch & Learns are held in Room 103 of the Bryan Research Building on Research Drive (not Bryan Center) from Noon until 1:00 PM with no registration necessary. Beverages and desserts are provided - please feel free to bring your lunch.

June 11, 2007 **"Do's and Don'ts of Serious Adverse Event Reporting"** **Speaker: Gerard A. Esposito, RN**

If you have questions please contact Pam Riley at pam.riley@duke.edu or 668-5928.

We would like your suggestions for topics in future issues of the NCRO Newsletter! Please send your suggestions to: JoAnn Jones @ jones018@mc.duke.edu.