

NCRO HIGHLIGHTS

**Duke
Neuroscience**

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



April 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
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ACTIVE ENROLLING STUDIES

The NCRO currently supports **44** 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-4/30/07
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 / 61
SCOTT, Burt	Boehringer Ingelheim	PD tx'd with Mirapex / other anti-PD agents	BI 248.619 Dominion	Field 668-2842	75-225 / 58
SCOTT, Burt	EISAI	PD	E2007-A001-302	Heydt 668-2843	25 / 2
SCOTT, Burt	Merz Pharmaceuticals	Cervical Dystonia	MRZ 60201-0408	Heydt 668-2843	6-8 / 4
SCOTT, Burt	NIH/NINDS	PD – early treated	Creatine (LS-1)	Grace 668-2844	36 / 0
STACY, Mark	Novartis	PD	Quest	Field 668-2842	10 / 1
STACY, Mark	Ceregene	Idiopathic PD	PD(CELC200AUS11) Cere-120-02	Gauger 668-1538	6-8 / 2

MULTIPLE SCLEROSIS

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

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 / 2
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NON-NCRO TRIALS

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 / 3

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

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

J. Burke (PI) – GSK 102672 (Reflect 2)

“A 54-week, double-blind, randomized, placebo-controlled, parallel-group study to investigate the effects of rosiglitazone (extended release tablets) as adjunctive therapy to donepezil on cognition and overall clinical response in APOE ε4-stratified subjects with mild to moderate Alzheimer’s disease”

The primary objective of this study is to investigate the add-on effects of daily dosing for 48 weeks with Rosiglitazone XR (extended release) tablets vs. placebo on cognitive function and overall clinical response in Donepezil-treated subjects with mild to moderate Alzheimer’s disease (AD), and to define the APOE ε4 allele-dependence of efficacy. A previous study suggested that Rosiglitazone XR may be effective in a genetically defined subset of patients with mild to moderate AD. We anticipate recruiting up to 15 subjects at Duke diagnosed with probable AD on at least 6 months of ongoing Donepezil therapy with stable dosing for at least the last two months. You may contact Dr. Jim Burke or Deb Heydt (668-2843) if you have a patient who may be interested in participating in this trial.

B. Scott (PI) – NET-PD Long-term Study-1 (LS-1)

“A multicenter, double-blind, parallel-group, placebo-controlled study of creatine in subjects with treated Parkinson’s disease (PD)”

The primary objective of this study is to determine if Creatine is more effective than placebo in slowing the clinical decline in Parkinson’s disease (PD) patients with early, treated PD. Creatine supplementation was shown to be well tolerated and “non-futile” for PD treatment in a previous NINDS-sponsored study and has been selected as a promising agent for this long-term clinical trial. We anticipate recruiting up to 36 subjects at Duke diagnosed with early PD. Subjects will stay on study drug for a minimum of 5 years or until the last subject enrolled completes 5 years on drug. The minimum 5 year duration should allow sufficient time to determine if the two groups differ in disease progression with continued followup beyond 5 years to provide longer term information on progression for a subset of subjects. You may contact Dr. Burt Scott or Karen Grace (668-2844) if you have a patient who may be interested in participating in this trial.

**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 TBD

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.