

NCRO HIGHLIGHTS

Duke
Neuroscience

Neuroscience Clinical Research Organization

Division of Neurology
Department of Medicine
Duke University Health System



September 2004

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

Who's Who in NCRO

Management	Coordination	Email:
Carmelo Graffagnino, Medical Director	Kate Beck 668-2278	beck0002@mc.duke.edu
Mark Stacy, Director of Operations	Yong Choi 668-2844	choi0001@mc.duke.edu
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JoAnn Jones, Regulatory Administrator	Sarah Wyne 668-2837	wyne0001@mc.duke.edu

SPOTLIGHT – New Approved Studies Ready for Recruitment!!

If you have patients who may be interested in participating in the below-referenced studies, please contact the individuals listed below – Thank you for your Support!

J Burke (PI) – GSK (49653:461)

“A double-blind, randomized, placebo-controlled, parallel-group study to investigate the effects of rosiglitazone (extended release tablets) on cerebral glucose utilization and cognition in subjects with mild to moderate Alzheimer’s Disease (AD)”

Study will examine the use of rosiglitazone XR in AD. Minimum PHI used for screening includes: diagnosis of probable AD; age between 50-85; MMSE score between 16 and 26; absence of diabetes mellitus, stroke, epilepsy, and moderate or greater congestive heart failure. Subjects will be randomized to receive a 12 month course of rosiglitazone XR (4 mg once a day for 1 month increasing to 8 mg once a day) or matched placebo. Subjects are permitted to continue on commonly used medications for AD including cholinesterase inhibitor, vitamin E, ginkgo biloba and memantine if dosing has been stable for >90 days. Subjects will be offered enrollment into an open label extension study following completion. We estimate to recruit 15 subjects here at Duke. **NOTE: In the last 2 years more than 4,000 visits for AD/Cognitive disorders were recorded by the PDC. Contact Jim Burke or Kristen Linney (668-2843) if you have a patient who may be interested in this study.**

A Husain (PI) – Schwarz (SP 754)

“A multicenter, double-blind, randomized, placebo-controlled, parallel group trial to investigate the efficacy and safety of SPM 927 (400 and 600 mg/day) as adjunctive therapy in subjects with partial seizures with or without secondary generalization”

Study will evaluate efficacy and safety of SPM 927 as adjunctive therapy in subjects with partial seizures. Minimum PHI used for screening includes: age between 18-70; are taking at least one but no more than 3 antiepileptic medications; have experienced seizures for at least 2 years; are experiencing an average of 4 or more seizures per month. Subjects will be randomized to one of three study arms (placebo, SPM 927 400 mg/day, or SPM 600 mg/day). Trial duration will be up to 29 weeks (includes an 8 week baseline phase and up to a 21 week treatment phase). Subjects will be offered enrollment into an open label extension study following completion. We estimate to recruit 15 subjects here at Duke. **NOTE: In the last 2 years more than 400 visits for intractable epilepsy were recorded by the PDC. Contact Aatif Husain or Kate Beck (668-2278) if you have a patient who may be interested in the study.**

B. Scott (PI) – Kyowa (6002-US-018)

“A 12-week, double-blind, placebo-controlled, randomized, parallel-group, multicenter, fixed dose-response study to evaluate the efficacy and safety of 10, 20 and 40 mg/day oral doses of KW-6002 (Istradefylline) as treatment for parkinson’s disease in patients with motor response complications on levodopa/carbidopa therapy”

Study will evaluate the efficacy and safety of istradefylline compared to placebo in subjects with advanced PD. Minimum PHI used for screening includes: age \geq 30 years old; have a diagnosis of advanced PD; are currently being treated with levodopa/carbidopa for at least one year; have been on a stable PD regimen within normal therapeutic limits including levodopa/carbidopa for at least 4 weeks preceding randomization. Subjects will be randomized to one of the following study arms (placebo or istradefylline 10, 20 or 40 mg/day). Trial duration is between 14 and 20 weeks. Subjects will be offered enrollment into an open label study following completion. We estimate to recruit 8 subjects here at Duke. **NOTE: In the last 2 years more than 4,000 visits for Parkinson’s Disease were recorded by the PDC. Contact Burt Scott or Gail Cook (684-0865) if you have a patient who may be interested in the study.**

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.

ACTIVE ENROLLING STUDIES

The NCRO currently supports **41** 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-8/31/04
BURKE, Jim WHITE, Heidi	GlaxoSmithKline NIH	Mild to Moderate AD Mild cog. Impairment	Rosiglitazone XR Nicotine Tr of MCI	Linney 668-2843 Cook 684-0865	15 / 0 25 / 2

EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 /
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GENERAL

Hurwitz, Barrie	Berlex	RR-Multiple Sclerosis	Beyond	Wyne 668-2837	15 / 4
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MOVEMENT DISORDERS

HUSAIN, Aatif	Boehringer Ingelheim	Restless Legs	RLS	Beck 668-2278	8 / 1
MASSEY, Janice	Elan	Cervical dystonia	CD-AN072-401	R. Suddarth 684-5422	15 / 5
MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 0
STACY, Mark	Boehringer Ingelheim	Movement disorder	SCEPTRE	Gauger 668-1538	8 / 0
SCOTT, Burt	Physician Funded	Movement disorder	Visual Documentation	N/A	No Target / 433
SCOTT, Burt	Physician Funded	Movement disorder	Tetabenazine	N/A	No Target / 43
SCOTT, Burt	Wyeth Pharm	PD-ERT	POETRY	Moore 668-2842	5 / 0
SCOTT, Burt	Wyeth Pharm	PD-ERT	POEMS	Moore 668-2842	20 / 11
SCOTT, Burt	Kyowa	PD-motor response complications	KW-6002 (6002-US-018)	Cook 684-0865	8 / 0

NEUROMUSCULAR

BEDLACK, Rick	Carolinas Med Ctr	ALS	ALS-Creatine	Choi 668-2844	15 / 18
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 7

PSYCHIATRY

GOLI, Veeraindar	Celgene	Fibromyalgia	Thalidomide	Wyne 668-2837	30 / 3
GOLI, Veeraindar	Elan	Chronic severe pain	Chronic Pain-ZEST	Linney 668-2843	4 / 1
GOLI, Veeraindar	UCB Pharma	Postherpetic neuralgia	Levetiracetam PHN	Linney 668-2843	5 / 0
GOLI, Veeraindar	UCB Pharma	Fibromyalgia syndrome	Keppra	Wyne 668-2837	60 / 1

VASCULAR

BUSHNELL, Cheryl	NIH	Stroke	Hormone Repl. Therapy	Link 970-1648	150 / 123
GOLDSTEIN, Larry	AGA Med Corp	Cryptogenic stroke	RESPECT	Link 970-1648	10 / 0
GOLDSTEIN, Larry	Boehringer Ingelheim	Recurrent strokes	PRoFESS	Link 970-1648	30 / 0
GRAFFAGNINO, C	AstraZeneca-	Acute ischemic stroke	Stroke-SA-NXY-0007	Stoner 668-5275	10 / 7
GRAFFAGNINO, C	Centocor	Acute ischemic stroke	AbESTT II	Stoner 668-5275	12 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 352
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 36
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 2

CTQA LUNCH AND LEARN SERIES

2004-2005 Schedule

The lunch and learn series are one hour coordinator centric educational sessions with the primary goal of providing useful, hands on knowledge to build a stronger research work force. These sessions will also provide the members of the CTQA office an opportunity to present themselves as a resource to the research community.

August 19, 2004	Development of a Study Regulatory Binder
September 13, 2004	Preparing for FDA Inspections
October 4, 2004	Protocol Deviations
November 1, 2004	Subject Recruitment
December 06, 2004	The Consenting Process
January 10, 2005	Recognizing and Reporting Research Misconduct
February 14, 2005	Handling Monitoring Visits
March 14, 2005	Preparing Research Budgets
April 11, 2005	Basics of INDs
May 09, 2005	TBA
June 6, 2005	TBA

ALL SESSIONS ARE FROM 12:00-1:00pm AND HELD IN ROOM 103 BRYAN RESEARCH BUILDING. SEATING IS ON A FIRST COME, FIRST SERVED BASIS FOR THOSE WHO HAVE REGISTERED FOR THE SERIES.

PLEASE REGISTER FOR THE SERIES BY E-MAILING CTQA@MC.DUKE.EDU
BRING YOUR LUNCH, THE COMPLIANCE OFFICE WILL PROVIDE DRINKS AND DESSERTS!!