

NCRO HIGHLIGHTS

Neuroscience Clinical Research Organization

Duke
Neuroscience



Division of Neurology
Department of Medicine
Duke University Health System

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

November 2004

Who's Who in the NCRO

Management

Carmelo Graffagnino, Medical Director
Mark Stacy, Director of Operations
Ron Beauvais, Administrator
Donna Carnes, Regulatory Assistant
Sharon Dowell, Administrative Manager
Lisa Gauger, Clinical Research Administrator
JoAnn Jones, Regulatory Administrator

Coordination

Kate Beck 668-2278
Yong Choi 668-2844
Gail Cook 684-0865
Rene Link 970-1648
Kristen Linney 668-2843
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Please join us in welcoming Joanne Field, BSN, RN as the newest clinical research coordinator to the NCRO. Joanne has been at Duke 20 years and we're excited to welcome her aboard!

REGULATORY NEWS

Procedure for Advisory Board Review of Studies done Outside of the NCRO

Per Department of Medicine Rules, all new research study proposals must have Advisory Board approval prior to Division and Department signoffs. For studies that are run through the NCRO, this review is part of the internal review process. For studies done outside of the NCRO, the PI's office must proceed as follows:

- Submit the new study IRB application to JoAnn Jones (Duke Health Center @ Morreene Road, Rm. 233)
- An Advisory Board Reviewer will be selected to review the study (Advisory Board Reviewers are required to review all new studies for scientific and clinical validity as well as ethical validity and patient safety)
- If the Advisory Board Reviewer has any concerns prior to giving approval, he/she should contact the PI of the study directly for resolution
- The Advisory Board Reviewer will contact JoAnn Jones when approved and ready for pick up
- The study will then be stamped with Advisory Board Approval and the PI's office will be called for pick up to continue with signatures/IRB submission.

STUDY SPOTLIGHT

"A double-blind, randomised, placebo-controlled, parallel-group study to investigate the effects of rosiglitazone (extended release tablets) on cerebral glucose utilisation and cognition in subjects with mild to moderate Alzheimer's Disease (AD)"

Study Summary: Clinical data suggest that peroxisome proliferators-activated receptor gamma (PPAR gamma) agonists may be effective in alleviating the cognitive decline associated with Alzheimer's disease (AD). The primary objective of this study is to compare longitudinal changes over one year in cerebral fluoro-deoxyglucose (FDG) uptake between AD patients receiving the PPAR gamma agonist Rosiglitazone XR (Avandia XR; GSK) and placebo. The secondary objectives will be to compare the following measures in patients receiving one year treatment with Rosiglitazone XR or placebo: cognitive performance; structural changes in the brain by volumetric MRI; peripheral glucose metabolism; insulin sensitivity, and inflammatory markers.

Wanted: Patients with a diagnosis of Probable Alzheimer's disease. MMSE score 26-16. Age: >50 to <85 years.

Other Medications: Patients may be receiving cholinesterase inhibitors, Memantine, and Gingko Biloba if on a stable dose for >90 days.

Excluded Conditions: Diabetes mellitus, stroke, epilepsy, congestive heart failure.

If you have a patient that you think may be eligible, just call or email and leave the patient's name and history number:

Kristen Linney – 668-2843 / linne003@mc.duke.edu (Study Coordinator)

Jim Burke – 684-5650 / james.burke@duke.edu (Principal Investigator)

We will do the rest. You do not have to call while the patient is in clinic. We will review the chart and talk to you before contacting the patient.

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).

DEMENCIA STUDIES

PI	SPONSOR	INDICATION	STUDY-ID	COORDINATOR	TARGET / # PTS ENROLLED-11/30//04
BURKE, Jim	GlaxoSmithKline	Mild to Moderate AD	Rosiglitazone XR	Linney 668-2843	15 / 0
WHITE, Heidi	NIH	Mild cog. Impairment	Nicotine Tr of MCI	Cook 684-0865	25 / 4

EPILEPSY

HUSAIN, Aatif	Schwarz	Epilepsy-partial seizures	SPM 927 (SP 754)	Beck 668-2278	5 / 0
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GENERAL

Hurwitz, Barrie	Berlex	RR-Multiple Sclerosis	Beyond	Wyne 668-2837	15 / 5
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MOVEMENT DISORDERS

HUSAIN, Aatif	Boehringer Ingelheim	Restless Legs	RLS	Beck 668-2278	8 / 2
MORGENLANDER, J	Private Investors	Restless Legs	RLS	N/A	20 / 3
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	Gauger 668-1538	5 / 0
SCOTT, Burt	Wyeth Pharm	PD-ERT	POEMS	Gauger 668-1538	38 / 27
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 / 21
BEDLACK, Rick	Columbia / NINDS	ALS	Minocycline	Choi 668-2844	15-20 / 0
MASSEY, Janice	FDA	Myasthenia Gravis	MG-Cellcept	Provided by Physician	10 / 7

PSYCHIATRY

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

VASCULAR

BUSHNELL, Cheryl	NIH	Stroke	Hormone Repl. Therapy	Link 970-1648	140 / 123
CHILUKURI, Vani	NIH / Wash Univ	Carotid occlusion	Surgery vs stan med care	Stoner 668-5275	30 / 0
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 / 8
GRAFFAGNINO, C	Centocor	Acute ischemic stroke	AbESTT II	Stoner 668-5275	12 / 1
GRAFFAGNINO, C	AstraZeneca	Acute ICH	CHANT-SA-NXY-0012	Stoner 668-5275	3-6 / 0
LASKOWITZ, Danny	Biosite	Biomarker-brain injury	Triage Stoke Panel	B. Blessing 970-4888	450 / 394
LASKOWITZ, Danny	Merck & Phys Funded	Aneurismal SAH	Simvastatin-SAH	B. Blessing 970-4888	120 / 41
LYNCH, John	Physician Funded	Traumatic brain injury	Simvastatin-TBI	B. Blessing 970-4888	100 / 5

**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.

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!!