NETT-WORKINGS

THE NEWSLETTER OF THE NEUROLOGICAL EMERGENCIES TREATMENT TRIALS (NETT) NETWORK

VOLUME 1, NO. 1, JANUARY 2007

PARTICIPATING HUBS AND INVESTIGATORS

Emory University
David Wright, MD
Henry Ford Hospital
Christopher Lewandowski, MD
Medical College of Wisconsin
Thomas Aufderheide, MD
Temple University
Nina Gentile, MD
University of Arizona
Kurt Denninghoff, MD
University of California, San Francisco
Claude Hemphill, MD
University of Cincinnati
Arthur Pancioli, MD
University of Kentucky
Roger Humphries, MD
University of Minnesota
Michelle Biros, MD
University of Pennsylvania
Jill Barren, MD
Wayne State University
Robert Welch, MD

CLINICAL COORDINATING CENTER (CCC)
University of Michigan
William Barsan, MD

STATISTICAL & DATA MANAGEMENT CENTER (SDMC)
Medical University of South Carolina
Yuko Palesh, PhD

National Institute of Neurological Disorders and Stroke (NINDS)
Clinical Trial Group
Robin Conwit, MD

JANUARY NETT INVESTIGATOR MEETING INFO!

The first NETT investigator, Steering Committee meeting will be held on January 30, 2007 at the Crowne Plaza Hotel in Romulus, MI. The hotel is within 1/2 mile of the Detroit Metro Airport and there is a complimentary shuttle provided by the hotel.

Lori Avers (lavers@umich.edu) is happy to assist you with your reservation. Reservations must be made before January 15, 2007. The hotel will continue to accept reservations after the 15th if rooms are available. A credit card or advance deposit is required to guarantee reservations.

Crowne Plaza Hotel
DETROIT-METRO AIRPORT
8000 Merriman Rd.
Romulus, MI 48174
Hotel Front Desk: 1-734-7292600 | General Reservations
1-800-980-6429
http://www.ichotelsgroup.com

NETT IN THE NEWS

We are very happy to announce that the Annals of Emergency Medicine includes an article on the NETT network. The article entitled, "*The birth of the NETT: NIH-funded network will launch emergency neurological trials,"* appears in the December issue of the journal.

Please feel free to share this news with your institutional partners, hub spokes, and public relations departments.

The article can be found on our NETT website:
http://www.nett.umich.edu/nett/files/the_birth_of_the_nett_article.pdf

Visit the NETT web site at nett.umich.edu

Looking Ahead…

RAMPART

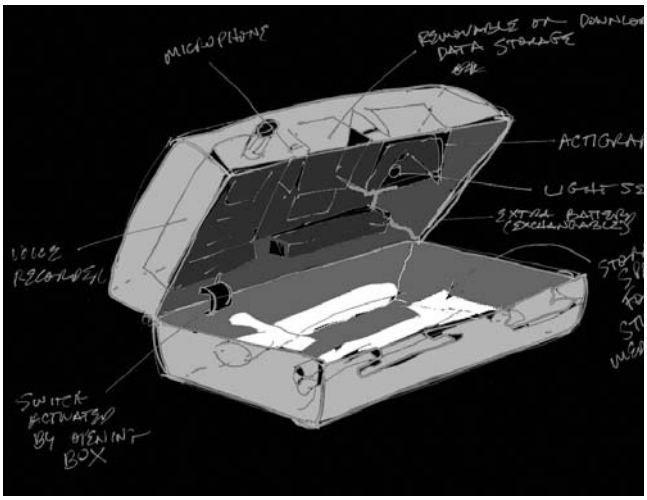
***(R**apid **A**nticonvulsant **M**edication **P**rior to **Ar**rival **T**rial)*

Seizures are a common cause of emergency medical services (EMS) activation. The objectives of the RAMPART study are to 1) determine the effectiveness and rapidity of intramuscular (IM) midazolam versus intravenous (IV) lorazepam in the pre-hospital treatment of status epilepticus and 2) examine the effects of IM midazolam versus IV lorazepam on subsequent clinical outcomes including frequency of endotracheal intubation, the frequency and duration of ICU admission, and the frequency and duration of pharmacologic coma.

The RAMPART study incorporates two distinct and challenging elements. First, a hallmark of this study is that it will be conducted under an IND for exception to informed consent for emergency research. The second feature is that EMS providers within the communities of the Hub complexes will have an active and crucial role in the conduct and success of this study.

Our enrollment target is 23 subjects per year at each Hub and spoke complex. Meeting this enrollment goal will allow the trial to be completed in 24 months.

THE RAMPART DATALOGGER BOX



INTERACT-*US*

***Inte**nsive Blood Pressure **R**eduction in **A**cute **C**erebral Hemorrhage **T**rial in the **U**nited **S**tates (INTERACT-US)*

Intracranial hemorrhage (ICH) affects over 37,000 people in the United States (US) and 2-3 million people elsewhere in the world each year. It is the most serious pathological type of stroke, with a case fatality of 40-50% and over half of survivors left permanently disabled.

High blood pressure (BP) is well established as the major risk factor for ICH, with several studies showing that BP levels are positively and continuously associated with risks of ICH. One potentially simple and widely applicable therapeutic approach to the management of ICH is the rapid control of elevated blood pressure, as BP levels are commonly acutely elevated and are associated with poor outcomes in ICH.

The INTERACT-*US* is a Phase II, randomized controlled trial to establish the feasibility of a management strategy of early intensive BP-lowering in patients with elevated systolic BP within 6 hours of onset of ICH.

Aims of the study include 1) determining the feasibility of an intensive blood pressure lowering regimen compared with control blood pressure management within one hour of randomization in the emergency department and 2) compare the results of this U.S. trial with a parallel study occurring in the Asia-Pacific region for the purpose of determining comparability for a future multi-national Phase III blood pressure lowering study for ICH.

Data from INTERACT-*US* will also be combined in a prospective pooled analysis with results from the INTERACT *Asia-Pacific* study, after first assessing for homogeneity of the results among the studies. Both studies will use the same open, prospective, randomized, controlled design, and have the same outcome measures and assessments. This aim is to generate reliable evidence that will guide clinical practice and future research as to the most appropriate BP management strategy in ICH.

PLEASED TO MEET YOU...

William G. Barsan, M.D.
Professor and Chair
Department of Emergency Medicine
University of Michigan, Ann Arbor

A native of Ohio, Dr. Barsan, attended the University of Cincinnati for his B.S. degree and the Ohio State University for medical school. He did two years of residency training in Surgery and Radiology at the University of Virginia before returning to the University of Cincinnati for residency training in Emergency Medicine. In 1979, he joined the faculty of the University of Cincinnati College of Medicine. While in Cincinnati, Dr. Barsan was a founding member of the Greater Cincinnati Northern Kentucky Stroke Team and has been involved in stroke clinical trials since 1985. Dr. Barsan accepted the position of Section Head of Emergency Medicine at the University of Michigan in 1992. He is currently professor and inaugural chair of the Department of Emergency Medicine at the University of Michigan and serves on the staff of several area hospitals. He is a past president of the Society for Academic Emergency Medicine ('91-'92) and the American Board of Emergency Medicine ('98-'99). In October 2003, Dr. Barsan was elected to the membership of the Institute of Medicine of the National Academy of Sciences. He was elected in May 2006 to the position of president of the Association for Academic Chairs in Emergency Medicine, and was elected in June 2006 to a 5-year position on the Hospitals and Health Centers Executive Board (HHCEB).

Dr. Barsan and his wife Mary have 3 children, David, Blake and Anna, who have all graduated from college and are working in the Ann Arbor area. They like spending time with family and taking long walks with their dog.

NIH GRANT SUBMISSION REMINDER

Beginning February 5, 2007 the NIH will require applicants to submit all Research Project Grant R01 applications electronically — no paper applications will be accepted. To view an application submission training webcast visit http://era.nih.gov/ElectronicReceipt/training.htm

ADMIN MINUTE
The Fly America Act

So…you have heard great things about British Airways and you plan on giving them a try on your next overseas excursion? You may want to reconsider if your next trip is part of a Federally sponsored project.

The "*Fly America Act*" refers to the provisions enacted by section 5 of the International Air Transportation Fair Competitive Practices Act of 1974. In a nutshell, the "Fly America Act" requires travelers whose air travel is being financed by the U.S. Government to use a designated U.S. flag air carrier service for all international air travel when it is available.

Examples of US flag carriers include: Airtran Airways, Alaska Airlines, America West Airlines, American Airlines, American Trans Air, Continental Airlines, Delta Airlines, Frontier Airlines, Hawaiian Airlines, Midwest Express, Northwest Airlines, Southwest Airlines, Spirit Airlines, United Airlines, and US Airways. There are times when there are exceptions to the rule. If you have additional questions please contact your grants office.

For more information on the Act check out: http://osr.unc.edu/documents/federal_travel.pdf

REGULATORY ROUND-UP
COLLECTION AND SUBMISSION OF REGULATORY DOCUMENTS

Federalwide Assurance and Local IRB information is being collected and verfied by the CCC. Please email your study staff contact information to Sue Burhop, Site Manager at burhops@med.umich.edu in order to expedite the process of collecting these documents.

Leonard Basobas, Education Coordinator and Site Monitor, will be in contact with each hub individually to discuss the collection of Human Subjects Protection Certicates and CVs.

An Exceptional Issue

Exception to Informed Consent for Emergency Research

The nature of neurological emergencies research, like that of resuscitation research, is such that effective therapies are likely to have therapeutic windows so short that clinical trials of these interventions cannot be accomplished with a meaningful and fully informed consent process. International medical ethics guidelines support the conduct of such research using an exception to the requirement for informed consent for emergency research, and since 1996 US Federal Regulations have described which trials are eligible for this exception and the additional processes to be used to safeguard subjects in these trials. We anticipate that trials requiring this exception will occur with regularity in NETT. We will be developing resources and methods that the network will need to provide to our Hubs in order to meet or surpass the appropriately rigorous requirements in the Federal 50.24 Exception to Informed Consent for Emergency Research regulations such as community consultations and public notification. We are also exploring the creation of a special Emergency Research Central IRB, and will facilitate local specialized IRB training.

Learn more about the exception to informed consent requirements by reading the draft FDA guidance at:
http://www.fda.gov/OHRMS/DOCKETS/98fr/06d-0331-gdl0001.pdf

NINDS Funding Opportunities
http://www.ninds.nih.gov/funding/funding_announcements/funding_opps.htm

Moving to Stardardize the Reporting of Advers Events: The Basal Adverse Event Report (BAER)

The NIH Clinical Research Policy Analysis and Coordination Program (CRpac), recognizing the issues related to non-uniformity of describing and reporting adverse events has formed the Federal Adverse Event Task Force (FAET). The task force, which includes members of the NIH, VA, DoD, FDA, CDC, OHRP and AHRQ are working to harmonize and streamline the process for reporting adverse events. Eliminating the variability in defining adverse events with terms such as “unanticipated” and “unexpected” by creating a common dictionary of terms is one focus of the FAET. One of the many benefits of the initiative is that IRB reporting for networks and multi-center clinical trials will become more consistent and the format of the reports more uniform. We will keep you posted on the progress of the FAET as developments are made public.

The CRpac website at http://crpac.od.nih.gov/ can provide more information on the program.

To learn more about the FAET via an online slide show go to:
http://www.hhs.gov/ohrp/sachrp/mtgings/mtg07-06/japresent/AdvEvnt_files/frame.htm

Have a question and unsure who to ask?
Email us at NETT-contact@umich.edu

Do you know who you would like to contact but don’t have his or her contact information?

Visit the roster on the NETT website at http://www.nett.umich.edu/nett/about_us for specific contact information