

**TATRC Highlighted Research News Article:
“North American Clinical Trials Network”**

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**Nation’s Largest Research Network for Spinal Cord Injury Set to Begin First
Clinical Trial**



The North American Clinical Trials Network has created the largest spinal cord injury active clinical trial database in the United States and will begin its first clinical trial in early 2010. Sites include:

1. **TMH** - The Methodist Hospital, Houston
2. **UTHSC** - University Texas Health Science Center, Houston
3. **Louisville** - University of Louisville
4. **Thomas Jefferson** - Thomas Jefferson University, Philadelphia
5. **Toronto** - University of Toronto
6. **Virginia** - University of Virginia, Charlottesville
7. **Maryland** - University of Maryland, Baltimore
8. **WRAMC** - Walter Reed Army Medical Center, Washington, D.C.
9. **Miami** - University of Miami

DMC-UTSPH - Data Management and Statistical Coordinating Center, University of Texas School of Public Health, Houston

PHARMA-UH - Pharmacological Center, University of Houston, College of Pharmacy

Image courtesy of Methodist Neurological Institute



Dr. Robert G. Grossman is the lead investigator for the North American Clinical Trials Network.

Image courtesy of the Christopher and Dana Reeve Foundation

Many treatments to limit or reverse the devastating results of spinal cord injury (SCI) have shown promise in the laboratory yet have never been brought to clinical trials because of the formidable infrastructure required to test and approve them for human use.

A unique partnership between the military and the Christopher Reeve Foundation is addressing this challenge. The U.S. Army Medical Research and Materiel Command's (USAMRMC) Telemedicine and Advanced Technology Research Center (TATRC) is supporting the development of the foundation's North American Clinical Trials Network (NACTN), which has created the largest SCI active clinical trial database in the United States and will begin its first trial in early 2010.

Explains Dr. Kenneth Curley, a neurotrauma research coordinator with USAMRMC, “There are often not enough new cases of SCI at any one site to obtain the number of patients needed to conduct clinical research. NACTN is unique in the United States because of its size, scope and standards that must be followed by every research site. NACTN investigators are also gathering information on the outcomes for hundreds of patients to compare the efficacy of treatment.”

NACTN was created in 2004 by the Reeve Foundation with a consortium of university hospital neurosurgical and neurorehabilitation teams. TATRC has supported NACTN since 2006. More than 330 patients with acute spinal cord injuries have been enrolled into the NACTN database, which is open as a resource to all SCI researchers. NACTN is collaborating with a similar network in Europe, which has a database of 1,800 patients.

NACTN’s first clinical trial is a Phase I trial to test the safety of the drug Riluzole in acute SCI. Laboratory studies have demonstrated that Riluzole protects nerve cells from the toxic cascade of events that occur in the minutes and hours after the initial trauma of SCI. The drug must be administered within the first 12 hours after injury. The trial will take place at eight hospitals, seven in the United States and one in Canada.

In preparation for the trial, NACTN is developing more sensitive neurological outcome assessment tools that can detect even small changes in neurological function, which will help determine whether a drug or surgical intervention is having a positive effect. All researchers and clinicians in the group are using the same protocols, same assessment, same training and one central data facility. Taken together, these efforts will enable them to conduct stronger studies that could have an impact on service members in the very near future.

The Phase I trial, including follow-up of patient outcomes, is expected to take one year. If Riluzole is proven safe at this stage, a larger Phase II trial will begin. The drug could possibly be available on the frontlines within three to five years.

For future trials of new therapy, NACTN is gearing up to serve as the first U.S. site for a clinical trial of an antibody that has improved recovery in experimental studies. The antibody blocks a regeneration-inhibiting molecule in myelin, the wrapping around nerve fibers.

Another goal of NACTN is to characterize the differences between military and civilian injuries and their treatment and outcome.

The lead investigator for NACTN is Robert G. Grossman, M.D., chair of the Department of Neurosurgery and director of the Neurological Institute of The Methodist Hospital, Houston.

“DOD funding has been critical for NACTN to expand,” says Grossman. “We now have nine clinical centers including Walter Reed Army Medical Center, and we plan to add additional military, VA and civilian hospitals. This will increase our capacity to conduct

high-quality trials with the statistical power to determine the effectiveness of emerging SCI therapies.”

Grossman is hopeful this global network will speed new therapies from the lab to the frontlines. “Clinical trials are very time consuming and expensive and must be designed carefully to obtain valid data,” Grossman says. “The key is collaboration. NACTN is a test-bed for clinicians and biomedical researchers to combine their knowledge and, ultimately, to help patients.”

Notes TATRC Chief Scientist Dr. Charles Peterson, “We are proud to support this effort because of the hope and promise it holds.”