

# RESEARCH & EDUCATION

## HP184 STUDY COMPLETED

The Regional Spinal Cord Injury Center of the Delaware Valley (RSCICDV) at Thomas Jefferson University, a cooperative program between Thomas Jefferson University Hospital and Magee Rehabilitation Hospital, recently participated in a study to evaluate the effect of HP184, an investigational medication, on improving motor function for individuals with motor incomplete chronic spinal cord injury. Results of this study will be reported in the future, following data analysis and publication. Thanks to all those who participated. A follow-up study is planned for the Fall/Winter 2006.

## RESEARCH PARTICIPANTS NEEDED

The SCI Center has developed a research tool to measure improvement in walking in persons with spinal cord injury. We are seeking volunteers to help us validate the scale and make sure it is reliable. Research participants must be motor incomplete and able to walk short distances with or without assistive devices or assistance. Subjects will be required to come to Magee Rehabilitation Hospital on 2 different occasions for about 2 hours each visit. Those who participate will be reimbursed \$100 per visit for travel expenses and provided with free parking.

If you are interested in participating or would like more information, please call **Mary Patrick, R.N.**, RSCICDV Project Coordinator, at **(215) 955-6579**.



## GRANT AWARDED



**Anthony Burns, M.D.**, Assistant Director of the RSCICDV, was recently awarded a grant from the American Paraplegia Society, titled "Peripheral Denervation Following Spinal Cord Injury" which uses Magnetic Resonance

Imaging (MRI) to study nerve function following spinal cord injury. After sustaining a spinal cord injury, the signals that travel from the brain to the body are interrupted. When the injury is severe enough, the individual is paralyzed and unable to feel his or her body below the injury. There is some evidence in the medical literature that nerve cells and nerves cut off from the brain become sick and some may even die. Despite being first described over 30 years ago, little is known about this process. It is important to understand this process better because treatments that restore signal conduction through the injured spinal cord, for example stem cell transplants, will require healthy nerves below the injured area. In this study, we want to use special MRI techniques to study how healthy the nerves are in the paralyzed muscles below a spinal cord injury. We hope to be able to identify which muscles are abnormal and how severely the nerves are affected. The information obtained will be important to know in order to maximize the beneficial effects of future treatments.

## CLINICAL TRIAL



The Regional Spinal Cord Injury Center of the Delaware Valley (RSCICDV) at Thomas Jefferson University is currently conducting a clinical trial to investigate the potential of a new therapy, BA-210 (Cethrin®), in acute spinal cord

injury. BA-210 is a recombinant protein drug, which acts as a Rho antagonist to promote neuroregeneration and neuroprotection in the Central Nervous System (CNS). BioAxone Therapeutics, Inc is sponsoring this trial. BioAxone Inc. has shown in animal studies that BA-210 reduces the damage from spinal cord injury and stimulates axon regeneration when applied to the spinal cord. Further, BA-210 applied to the dura mater can penetrate into CNS tissue. In this clinical trial, BA-210 will be applied to the surface of the dura mater of the spinal cord together with

Tisseel®, a fibrin sealant normally used to repair small dural tears.

This is a first in human study, which involves a single application of BA-210, during surgery within seven days following spinal cord injury. Male or female patients aged between 16 and 70 years with acute thoracic or cervical spinal cord injury (with no motor or sensory function in the sacral segment) can be enrolled. The primary goal of this study is to determine the safety and tolerability of BA-210 when administered in conjunction with fibrin sealant to the dura mater of the spinal cord. Also, this study is designed to determine the effects of BA-210 on neurological function in subjects with complete spinal cord injury. James Harrop, M.D. from the Department of Neurosurgery at Thomas Jefferson University will serve as the Principal Investigator.

## ONGOING RESEARCH of the RSCICDV

### Current

1. A phase I/IIa dose-ranging study to evaluate the safety, tolerability, and pharmacokinetics of BA-210 and the neurological status of patients following administration of a single extradural application of Cethrin® during surgery for acute and cervical spinal cord injury. *Sponsor: BioAxone Therapeutics Inc.*
2. Peripheral denervation following spinal cord injury (Using MRI to study nerve function following spinal cord injury). *Sponsor: American Paraplegia Society*
3. Restoration of walking after spinal cord injury - elements of a disability measure. *Sponsor: National Institute on Disability and Rehabilitation Research (NIDRR).*
4. Restoration of walking after spinal cord injury - a consumer preference for walking. *Sponsor: National Institute on Disability and Rehabilitation Research (NIDRR).*

### Completed Clinical Trials

1. Open-label extension of double-blind, placebo-controlled, parallel group study to evaluate safety, tolerability and activity of oral Famipridine-SR in subjects with chronic incomplete spinal cord injury. *Sponsor: Acorda Therapeutics.*
2. Restoration of walking after spinal cord injury - validation of the Walking Index for Spinal Cord Injury (WISCI) scale for hierarchical ranking. *Sponsor: National Institute on Disability and Rehabilitation Research (NIDRR).*
3. Study the effects of Body Weight Supported Treadmill Training in acute incomplete spinal cord injury. *Sponsor: National Institute of Health (NIH).*
4. A multi-site, open label study to evaluate 250 mg oral Neotrofin™ BID in patients with subacute complete spinal cord injury over 12 weeks. *Sponsor: NeoTherapeutics, Inc.*
5. Double-blind, placebo-controlled, 12-week, parallel group study to evaluate safety and efficacy of oral Fampridine-SR in subjects with moderate to severe spasticity resulting from chronic, incomplete spinal cord injury. *Sponsor: Acorda Therapeutics.*
6. Eye-voice enablement technology: EVENTech, hands-free computer access for the disabled. *Sponsor: National Institute of Health.*
7. A phase II, double-blind, placebo-controlled, multicenter study to assess the efficacy and safety of HP184 at 100, 200, and 400 mg doses administered orally once daily for twenty-four weeks in adult subjects with chronic spinal cord injury. *Sponsor: Aventis Pharmaceuticals.*