

press releases



Mayfield Neurosurgeon to Study New Drug Aimed at Limiting Disability Following Spinal Cord Injury

CINCINNATI- [Charles Kuntz, IV, M.D.](#), a neurosurgeon with the Mayfield Clinic and The Neuroscience Institute at the University of Cincinnati and University Hospital, has joined a multi-site study of a drug that he and other researchers hope will limit disability following spinal cord injury.

The drug, a recombinant protein known as Cethrin®, has been shown in animals to limit the devastating process of cell death that occurs following spinal cord injury and to elicit repair of damaged neurons. This is the first study of Cethrin® in human beings.

Dr. Kuntz is principal investigator in the Cincinnati portion of the clinical trial, which seeks to determine the safety and the most effective dose of Cethrin® when administered during surgery following acute injury to the spinal cord in the neck (cervical spine) or upper back (thoracic spine). The research also will evaluate how Cethrin® works in the body. An investigational drug, Cethrin® has not been approved by the United States Food and Drug Administration.

"Spinal cord injuries are among the most devastating and tragic conditions we treat," said Dr. Kuntz, an associate professor of neurosurgery at UC. "In a flash, an individual's life is forever changed, and he or she is faced with a lifetime of dependency on machines. Finding a mechanism for reducing cell death – and thus limiting the extent of a patient's long-term disability – is something we have long wished for.

"Because this drug has not been studied before in humans, we do not know whether or not it will limit long-term disability in patients with acute spinal cord injuries," Dr. Kuntz continued. "We hope that it will."

Spinal cord injury occurs when the spinal cord, a bundle of nerves that runs down the back from the base of the brain to the waist, is damaged or severed by trauma. If the spinal cord is damaged and is unable to transmit nerve impulses to and from the brain, paralysis occurs.

The Foundation for Spinal Cord Injury Prevention, Care & Cure estimates that about 11,000 new spinal cord injuries result in the United States each year, about 40 cases for every million people. Motor vehicle crashes, falls, sports, violence, and shallow-water diving are primary causes. An estimated 250,000 Americans are currently living with spinal cord injury.

Following a spinal cord injury, two profound biological events occur: 1) damaged neurons are unable to regenerate their severed axons, the long fibers of communication between the brain and spinal cord that carry sensation and movement signals; and 2) there is an abnormal activation of the protein Rho , resulting in cell death.

Scientists have long dreamed of finding a way to disrupt the cataclysmic process of cell death that follows spinal cord injury and results in a life of dependency and permanent disability. For decades typical treatment has involved stabilizing the spine following an acute spinal cord injury, but surgeons had no technologies or medications with which to halt subsequent damage.

In research done on animals, the drug BA-210 (Cethrin®) helped repair the spinal cord after an injury by preventing nerve cell death and by stimulating the cells to regenerate their axons. Researchers say Cethrin®'s mechanism of action blocks activation of Rho , a key protein that regulates both regeneration and cell

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survival

The clinical trial is for patients between the age of 18 and 70 who have suffered a severe spinal cord injury to the upper back or neck that requires spinal surgery within seven days of the injury. Study participants will be followed for six months.

Up to 48 patients will participate in the trial at as many as 10 different sites in the United States and Canada . Up to six patients will be enrolled in Cincinnati .

Patients enrolled in the study will be placed into one of four groups. Each group will receive a different dose of Cethrin®. The dose, which will be dependent upon when the patient is enrolled, will be applied to a thin layer of tissue, called the dura mater, which covers the spinal cord.

Spinal cord injuries have profound human and financial costs. While the lifetime medical expenses for a person paralyzed from the neck down can reach \$2 million, it is the patient's tragic, life-altering paralysis that is most devastating, Dr. Kuntz said.

All spinal cord injury treatments carry risks. The most likely risks associated with this study could include allergic reactions to a sealant used to keep Cethrin® in place, kidney problems, abnormally low blood pressure, inflammation, hemorrhage, and liver changes.

The drug's manufacturer, BioAxone Therapeutic, Inc., of Montreal , is funding the study. Dr. Kuntz has no financial interests or holdings in BioAxone Therapeutic, Inc.

The Neuroscience Institute is a regional center of excellence that embraces nine specialties related to the spine, head, neck and brain. The Institute, located at The University Hospital and the University of Cincinnati , and affiliated with the Health Alliance, is dedicated to patient care, research, education, and the development of new medical technologies.

The Mayfield Clinic is recognized as one of the nation's leading physician organizations for clinical care, education, and research of the spine and brain. Mayfield, which is affiliated with the UC Department of Neurosurgery, includes 18 neurosurgeons and treats 20,000 patients from 35 states and a dozen countries in a typical year. Mayfield's neurosurgeons are active participants in important clinical trials and have pioneered surgical procedures and instrumentation that have revolutionized the medical art of neurosurgery for brain tumors and neurovascular diseases and disorders.

The University Hospital is part of the Health Alliance, an integrated health care delivery system that also includes The Christ Hospital, The St. Luke Hospitals, The Jewish Hospital, Fort Hamilton Hospital , and the physicians of Alliance Primary Care. To view other Health Alliance news releases, go to www.health-alliance.com/pressroom.

For more information about the Cethrin® study, including complete details about eligibility and risks, go to: http://www.mayfieldclinic.com/CT_bioaxone.htm.

Patients or family members wishing to enroll in the study can contact Suzanne Kempisty, R.N., at (513) 558-3590 or Suzanne.kempisty-cliver@uc.edu.

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