

Regenerating nerve tissue in spinal cord injuries

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Researchers at Rush University Medical Center are exploring a new therapy using stem cells to treat spinal cord injuries within the first 14 to 30 days of injury. Rush is only the second center in the country currently studying this new approach.

The therapy uses a population of cells derived from human <u>embryonic</u> <u>stem cells</u> containing progenitor cells that support nerve cells and can potentially make poorly functioning nerves function better.

"There are currently no therapies which successfully reverse the damage seen in the more than 12,000 individuals who suffer a <u>spinal cord</u> injury each year in the United States alone," says Dr. Richard G. Fessler, professor of neurological surgery at Rush University Medical Center and principal investigator for the Phase 1 clinical trial involving AST-OPC1 (oligodendrocyte progenitor cells). An estimated 1.3 million Americans are living with a spinal cord injury.

"These injuries can be devastating, causing both emotional and physical distress, but there is now hope. This is a new era where we are now able to test whether a dose of <u>stem cells</u> delivered directly to the injured site can have an impact on motor or sensory function," says Fessler. "If we could generate even modest improvements in motor or <u>sensory function</u>, it would result in significant improvements in quality of life."

The clinical trial is designed to assess safety and activity of escalating doses of the special cells (AST-OPC1) for individuals with a complete



cervical spinal cord injury. Thus far, one individual has been enrolled in the study at Rush. "The <u>surgical procedure</u> to inject AST-OPC1 went very well and there were no intraoperative complications," says Fessler.

The trial involves testing three escalating doses of AST-OPC1 in patients with subacute, C5-C7, neurologically-complete cervical spinal cord injury. These individuals have essentially lost all sensation and movement below their injury site with severe paralysis of the upper and lower limbs. AST-OPC1 is administered 14 to 30 days post-injury. Patients will be followed by neurological exams and imaging methods to assess the safety and activity of the product.

"In the future, this treatment may be used for <u>peripheral nerve injury</u> or other conditions which affect the spinal cord, such as MS or ALS," says Fessler.

For this therapy to work, the cord has to be in continuity and not severed, according to Fessler. The study seeks male and female patients ages 18 to 65 who recently experienced a complete cervical spinal cord injury at the neck that resulted in tetraplegia, the partial or total paralysis of arms, legs and torso. Patients must be able to start screening within 25 days of their injury, and participate in an elective surgical procedure to inject AST-OPC1 14 to 30 days following injury. Participants also must be able to provide consent and commit to a long-term follow-up study.

Provided by Rush University Medical Center

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