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Clinical trial offers hope to restore limb function in man with complete cervical spinal cord injury

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Physicians at Rush University Medical Center became the first in Illinois to inject AST-OPC1 (oligodendrocyte progenitor cells), an experimental treatment, into the damaged cervical spine of a recently paralyzed man as part of a multicenter clinical trial.

Dr. Richard G. Fessler, professor of neurological surgery at Rush University Medical Center, is principal investigator for the Phase 1/2a, multicenter clinical trial involving AST-OPC1 at Rush, one of six centers in the country currently studying this new approach.

Fessler injected an experimental dose of 10 million AST-OPC1 cells directly into the paralyzed man's cervical spinal cord in mid-August. These injected cells were derived from human embryonic stem cells. They work by supporting the proper functioning of nerve cells, potentially helping to restore the conductivity of signals from the brain to the upper extremities (hands, arms, fingers) in a recently damaged spinal cord.

Interim research results from the trial were announced earlier today at the 55th Annual Scientific Meeting of the International Spinal Cord Society (ISCoS), which is being held in Vienna, Austria, on September 14-16, 2016.

"Until now, there have been no new treatment options for the 17,000

new spinal cord injuries that happen each year," says Fessler. "We may be on the verge of making a major breakthrough after decades of attempts."

The next phase of the clinical research trial will involve a dose of 20 million oligodendrocyte progenitor cells, which is the highest dose being studied in this study involving patients who have recently suffered a complete cervical spinal cord injury.

"These injuries can be devastating, causing both emotional and physical distress, but there is now hope. In the 20 years of my research, we have now reached a new era where we hope to demonstrate through research that a dose of very specially made human cells delivered directly to the injured site can have an impact on motor or sensory function," says Fessler. "Generating even modest improvements in motor or sensory function can possibly result in significant improvements in quality of life."

Early research results from the trial were announced at the 55th Annual Scientific Meeting of the International Spinal Cord Society (ISCoS), which is being held in Vienna, Austria, on September 14-16, 2016.

"Our preliminary results show that we may in fact be getting some regeneration. Some of those who have lost use of their hands are starting to get function back. That's the first time in history that's ever been done," says Fessler. "Just as a journey of a thousand miles is done one step at a time, repairing spinal cord injuries is being done one step at a time. And, now, we can say that we've taken that first step."

The clinical trial is designed to assess safety and effectiveness of escalating doses of the special cells (AST-OPC1) in individuals with a complete cervical spinal cord injury. Thus far, three individuals have been enrolled in the study at Rush.

The trial has involved the testing of 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 potentially be used for peripheral nerve injury or other conditions which affect the spinal cord, such as MS," 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