Clinical study results offer hope after spinal cord injury

September 23 2016, by Nancy Difiore And Kevin Mckeough

Richard Fessler, MD, PhD, says that the field of treating spinal cord injuries may be on "the verge of making a major breakthrough after decades of attempts."

A professor of neurological surgery at Rush, Fessler leads a multisite clinical study of a cell treatment for patients with complete cervical spinal cord injury that results in a total lack of sensory and motor function below the level of injury. On Sept. 14, Asteria Biotherapeutics, the biotechnology company that manufactures the treatment, announced early results showing that all five of the first patients in the study had achieved at least one motor level of improvement and that two of the patients had achieved two motor levels of improvement.

"The results to date … while still early, demonstrate meaningful improvement in motor function, particularly in the use of a patient's hands, fingers and arms, which is critically important for a patient's quality of life and ability to function independently," says Steve Cartt, president and CEO of Asterias.

"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," Fessler says.

Improving quality of life for 17,000 injured each year

According to Asterias, existing research suggests that patients with complete cervical spinal cord injuries that show two motor levels of improvement on at least one side may regain the ability to perform daily activities such as feeding, dressing and bathing.

"Until now, there have been no new treatment options for the 17,000 new spinal cord injuries that happen each year," Fessler says. "Generating even modest improvements in motor or sensory function can possibly result in significant improvements in quality of life."

Fessler is the principal investigator of the Phase 1/2a, multicenter clinical trial of Asterias' line of oligodendrocyte progenitor cells, or AST-OPC1. He is the only physician in Illinois to inject AST-OPC1, an experimental treatment, into the damaged cervical spine of a recently paralyzed man as part of the study.

Rush is one of six centers in the country currently studying this new approach. Fessler is the study's lead investigator of all of the sites involved in the study.

In the latest phase of the study, Fessler injected a dose of 10 million AST-OPC1 cells directly into the paralyzed man's cervical spinal cord in mid-August. These cells support 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.

'There was my friend, unable to move'

Fessler has devoted himself to finding a treatment for spinal cord injury for 20 years. His dedication to his mission was inspired by a paralyzing injury a college wrestling teammate sustained during practice.

"I heard a crunch," Fessler remembers. "I turned around, and there was my friend, my fraternity brother, unable to move. He remained paralyzed from the neck down for the rest of his life."

"These injuries can be devastating, causing both emotional and physical distress, but there is now hope," Fessler says. "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."

Treatment may be used for nerve injuries and MS someday

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

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 within 14 to 30 days after the injury. The patients are 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 (multiple sclerosis)," Fessler says.

Next phase of study will use 20 million cells

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.

The next phase of the clinical research trial will involve a dose of 20 million AST-OPC1, which is the highest dose being studied in this study. More information on the study can be found at www.scistar-study.com .

Provided by Rush University Medical Center