Nation's second participant enrolls in human embryonic stem cell trial

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Researchers at Northwestern Memorial Hospital, Northwestern University Feinberg School of Medicine and The Rehabilitation Institute of Chicago (RIC) recently enrolled their first subject in a national clinical research trial of a human embryonic stem cell-based therapy for participants with a subacute thoracic spinal cord injury. This is only the second enrollment nationwide in the study sponsored by Geron Corp. Northwestern is one of five sites currently open for subject enrollment. The trial will enroll up to 10 subjects nationally.

“We are very excited to announce the second enrollment in this milestone study, which is the first to evaluate the effects of cells derived from embryonic stem cells in subjects with severe spinal cord injuries,” said lead national investigator Richard Fessler, MD, PhD, surgeon at Northwestern Memorial and professor of neurological surgery at the Feinberg School. “Injection of oligodendrocyte progenitor cells directly into the spinal cord lesion is a rational way to attempt to arrest or reverse the structural damage in the spinal cord caused by severe trauma.”

The participant received an injection of cells over the weekend at Northwestern Memorial and will now undergo a progressive course of rehabilitation care and intervention at RIC.

“RIC's team of spinal cord injury rehabilitation specialists customize each patient's rehabilitation care plan, which may include robotic walking therapy and other procedures to facilitate the participant's neurologic repair and recovery,” said David Chen, MD, medical director

of the RIC Spinal Cord Injury Rehabilitation Program. “At RIC, restoring a patient's ability is our objective and the scientific application of embryonic stem cells offers exciting new hope for recovery.”

The primary objective of the Phase I trial is to assess the safety and tolerability of special cells called oligodendrocyte progenitor cells, derived from human embryonic stem cells, when they are injected into the spinal cord injury of paralyzed subjects. The injuries must have occurred within two weeks for someone to be eligible for the procedure. In addition to evaluating safety, the secondary aim of the trial is to see if the stem cells improve neuromuscular control or sensation in the trunk or lower extremities.

“The first recipient receiving the injection of oligodendrocyte progenitor cells more than six months ago has not experienced any serious adverse events attributed to the stem cell transplant to date,” said Fessler. “It remains too early in the trial to determine improvement in neuromuscular control or sensation.”

In previous animal studies, these stem cells have demonstrated the ability to remyelinate or recoat damaged nerve cells that have lost their ability to conduct electrical impulses down the axon. The stem cells also have shown nerve-growth stimulating properties leading to restoration of function in animal models of acute spinal cord injury. Subjects eligible for the Phase I trial will have documented evidence of functionally complete (ASIA Impairment Scale grade A) spinal cord injury with a neurological level of T3 to T10 spinal segments and agree to have GRNOPC1 injected into the lesion sites between 7 and 14 days after injury.

Provided by Northwestern University