Northwestern first site open for spinal cord stem cell trial

22 September 2010

Northwestern Medicine is the first site open for enrollment in a national clinical research trial of a human embryonic stem cell-based therapy for participants with a subacute thoracic spinal cord injury. Following the procedure, participants will receive rehabilitation treatment at The Rehabilitation Institute of Chicago (RIC).

Northwestern also is the lead site of the trial, sponsored by Geron Corporation (Nasdaq: GERN). The trial eventually will include up to six other sites and enroll up to 10 participants nationally.

"We are very pleased to be the first participating center in the world's first human embryonic stem cell clinical trial for spinal cord injury," said lead national investigator Richard Fessler, M.D., professor of neurological surgery at Northwestern University Feinberg School of Medicine and a surgeon at Northwestern Memorial Hospital.

"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," Fessler said. "We are eager to begin evaluating the effects of these cells in subjects with severe spinal cord injuries."

"RIC is a vital member of the research team for this novel stem cell clinical trial," said David Chen, M.D., medical director of the RIC Spinal Cord Injury Rehabilitation Program. "RIC's team of spinal cord injury rehabilitation specialists is responsible for customizing the rehabilitation care plan and therapeutic intervention for each participant, which may include robotic walking therapy and other procedures to facilitate the participant's neurologic repair and recovery. At RIC, restoring the participant's ability is our objective and the scientific application of embryonic stem cells offers new hope for recovery."

The primary objective of the phase I trial is to assess the safety and tolerability of special cells called human embryonic stem cell-derived oligodendrocyte progenitor cells when they are injected into the spinal cord injury of paralyzed subjects. The injuries have to 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.

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.

"The trial is supported by positive animal research," Fessler said. He noted the trial is using the lowest dose possible for a human based on the animal studies.

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