MedicalXpress

Swiss agency approves clinical trial of UCI-created neural stem cell therapy

December 7 2010

A therapy developed by Aileen Anderson and Brian Cummings of UC Irvine's Sue and Bill Gross Stem Cell Research Center in collaboration with researchers at StemCells Inc. will be the basis of the world's first clinical trial using human neural stem cells to treat spinal cord injury.

Swissmedic, the Swiss regulatory agency for therapeutic products, has authorized a Phase I/II clinical trial for chronic spinal cord injury, cases in which inflammation has stabilized and recovery has reached a plateau.

The trial will utilize StemCells Inc.'s proprietary purified human neural stem cells and will be conducted at the University of Zurich's University Hospital Balgrist, one of the world's leading medical centers for spinal cord injury and rehabilitation.

It's designed to assess both safety and preliminary efficacy in patients with varying degrees of paralysis who are between three and 12 months post-injury at the time of transplantation. Enrollment is expected to begin in early 2011.

"This is tremendously exciting news," said Anderson, UCI associate professor of physical medicine & rehabilitation and anatomy & neurobiology. "Human neural stem cells may hold great promise for helping people with spinal cord injuries regain lost function."

In their collaboration with StemCells Inc., Anderson and Cummings conducted eight years of preclinical studies in rodents that demonstrated

the significant therapeutic potential of human neural stem cells.

Their efforts have shown how these cells, when transplanted into damaged spinal columns, can differentiate into neural tissue cells – such as oligodendrocytes and early neurons – and migrate to injury sites. In recent studies, the researchers found that the treatment restored hind-limb function in mice when transplanted in the early chronic period after spinal cord injury.

Other stem cell studies have focused on the acute, or early, phase of spinal cord injury, a period of up to a few weeks after the initial trauma when drug therapies can lead to some functional recovery. The Swiss trial is significant because it will test treatment safety and restoration of mobility during the chronic, or later, phase. There are currently no drug therapies to help restore function during this phase.

"About 1.3 million individuals in the U.S. are living with chronic spinal cord injury," said Cummings, UCI associate professor of physical medicine & rehabilitation and anatomy & neurobiology. "This trial will be the first opportunity to demonstrate that human neural stem cells may be a viable treatment approach for them."

Provided by University of California - Irvine