

August 11, 2014 | By Jackie Carr

Clinical Trial Evaluates Safety of Stem Cell Transplantation in Spine

Researchers at the University of California, San Diego School of Medicine have launched a clinical trial to investigate the safety of neural stem cell transplantation in patients with chronic spinal cord injuries. This Phase I clinical trial is recruiting eight patients for the 5-year study.

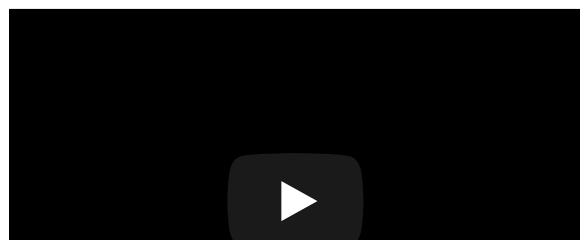
“The goal of this study is to evaluate the safety of transplanting neural stem cells into the spine for what one day could be a treatment for spinal cord injuries,” said Joseph Ciacci, MD, principal investigator and neurosurgeon at UC San Diego Health System. “The study’s immediate goal, however, is to determine whether injecting these neural stem cells into the spine of patients with spinal cord injury is safe.”

Related goals of the clinical trial include evaluating the stem cell graft’s survival and the effectiveness of immunosuppression drugs to prevent rejection. The researchers will also look for possible therapeutic benefits such as changes in motor and sensory function, bowel and bladder function, and pain levels.

Patients who are accepted for the study will have spinal cord injury to the T7-T12 level of the spine’s vertebrae and will have incurred their injury between one and two years ago.



Joseph Ciacci, MD, principal investigator and neurosurgeon at UC San Diego Health System



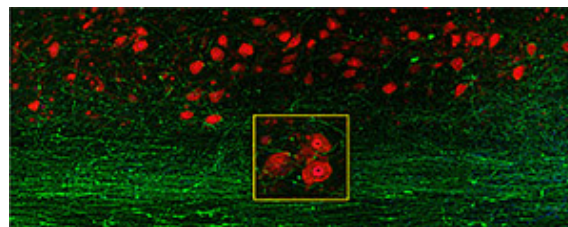
All participants will receive the stem cell injection. The scientists will use a line of human stem cells approved by the U.S. FDA for human trials in patients with chronic traumatic spinal injuries. These cells were previously tested for safety in patients with amyotrophic lateral sclerosis (ALS).



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Since stem cell transplantation for spinal cord injury is just beginning clinical tests, unforeseen risks, complications or unpredictable outcomes are possible. Careful clinical testing is essential to ensure that this type of therapy is developed responsibly with appropriate management of the risks that all medical therapies may present.

Pre-clinical studies of these cells by Ciacci and Martin Marsala, MD, at the UC San Diego School of Medicine, showed that these grafted neural stem cells improved motor function in spinal cord injured rats with minimal side effects indicating that human clinical trials are now warranted.



Rodents with spinal cord injury show extensive growth of neuronal axons (green) from human neural stem cells that are transplanted into the area of a spinal cord injury. The red shows development of synapses-like structures between the new transplanted cells and the nerve cells that remained after the injury. The purpose of the Phase 1 clinical trial is to test of safety of injections in humans.

This clinical trial at UC San Diego Health System is funded by Neuralstem, Inc. and was launched and supported by the UC San Diego Sanford Stem Cell Clinical Center. The Center was recently created to advance leading-edge stem cell medicine and science, protect and counsel patients, and accelerate innovative stem cell research into patient diagnostics and therapy.

To learn more about eligibility for this clinical trial, please call Amber Faulise at 858-657-5175 or email her at rfaulise@ucsd.edu

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