

# Stanford team treats final patient in landmark stem cell therapy trial

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(Medical Xpress) -- The Stanford University School of Medicine and Santa Clara Valley Medical Center treated the fifth patient in the Geron Corp-sponsored trial of a human embryonic-stem-cell-derived treatment for severe spinal cord injury on Nov. 16.

The patient, who is the second to be treated at Stanford and SCVMC, was enrolled in the trial before Geron announced on Nov. 14 that it was discontinuing the trial. The patient elected to undergo the procedure after being informed of the trial's status.

“The procedure went smoothly and the patient is doing extremely well,” said Stanford neurosurgeon Gary Steinberg, MD, PhD. “Although the decision by Geron to discontinue the trial was disappointing, I am confident that stem cell science will continue to move forward as we and others work to translate promising laboratory findings into clinical benefits for [patients](#).” Steinberg, the Bernard and Ronni Lacroute-William Randolph Hearst Professor in Neurosurgery and Neurosciences at Stanford, is the principal investigator of the Stanford/SCVMC portion of the trial, and implanted the cells in the patient at the Rehabilitation Trauma Center at SCVMC.

Geron, based in Menlo Park, Calif., developed and manufactured the cells. The phase-1 trial was designed to test the safety of the cells in human patients. Although Geron has discontinued the trial to instead focus on new cancer treatments, the company will continue to monitor the five patients who have received the cells for a total of 15 years and is

actively looking for partners to “enable further development of its stem cell programs.”

The first patient in the multisite trial was treated at the Shepherd Center in Atlanta in October 2010; the first patient in the Stanford/SCVMC portion of the trial was treated Sept. 17.

The cells and procedure were well-tolerated by the previous four patients, and no serious adverse events have been observed. According to a statement from Geron, company officials decided to discontinue the trial because of financial considerations.

The Geron trial is the first to implant cells derived from human embryonic stem cells into human patients. A Santa Monica-based company, Advanced Cell Technology, has since launched two clinical trials to test other human embryonic-stem-cell-derived cells in patients with a form of juvenile blindness and a type of macular degeneration.

For the spinal cord injury trial, researchers at Geron collaborated with Hans Keirstead, PhD, and his laboratory team at UC-Irvine to develop a way to coax human embryonic stem cells to become a mixture of cells that include oligodendrocyte precursors. Oligodendrocytes are cells in the brain and the central nervous system that wrap nerve cells with an insulating material called myelin. This myelin sheath is necessary for the transmission of the electric signals along the spinal cord that trigger muscles to move, and relay our sense of touch and temperature. Damage to this sheath caused by trauma is a common cause of paralysis.

The trial was limited to patients with recent (within 14 days of injury) non-penetrating damage to a specific region of their thoracic spine — an area roughly from the top of the shoulder blades to the bottom of the rib cage. The damage needed to have caused complete paraplegia, meaning that the patients had normal sensation or movement to the level of the

hands, but not from the trunk to the toes.

During the Nov. 16 procedure, Steinberg applied about 2 million of the special cells, called GRNOPC1, directly into the injured area of the patient's spinal cord. After the procedure, the patient entered an intensive inpatient rehabilitation program under the supervision of [spinal cord](#) injury expert Stephen McKenna, MD, director of the Rehabilitation Trauma Center at SCVMC.

“The future for stem cell research is bright,” said McKenna.

“Conducting the world's first clinical trial of human embryonic [stem cells](#) and showing that they have been safe is a historic milestone in this new and developing field. We are extremely proud of our accomplishment.”

Provided by Stanford University Medical Center

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