**LARGE U.S. STEM CELL TRIAL UNDERWAY FOR CHRONIC CERVICAL SCI**

A 52-patient Phase II clinical trial to measure the effect of neural stem cells in chronic cervical spinal cord injury began last week at the Miami Project. The trial, dubbed the Pathway Study, is sponsored by California-based Stem Cells, Inc., and is an expansion of a safety study of 12 patients with thoracic injuries; that work was done mainly in Zurich, Switzerland but included patients at two Canadian centers.

The first cervical patient was treated at the University of Miami Hospital by neurosurgeon Allan Levi. Two other centers have also signed on to the trial, University of Michigan Health System in Ann Arbor and Mount Sinai Medical Center in New York.

Besides being the largest stem cell trial to date in the SCI field, this new trial is significant in several ways.

- **First**, it addresses cervical injury. All previous stem cell studies have tested lower-level injuries. A thoracic implant runs a much lower risk for complications than an upper-level intervention (think about losing or gaining two segments of mid- or low-back function – this would not have any obvious effect. But lose or gain two levels of cervical function? Could be a huge life-changer, perhaps the difference between self-care and the need for an attendant). Most significantly for this trial, it will be much easier to assess improvement in cervical patients in terms of finger and hand dexterity.

- **Second**, the Pathway trial is not an acute trial. Enrollment is open to C-5 to C7 quads up to two years post-injury.

- **Third**, the trial is open to incomplete injuries (ASIA a, B, or C). You are a potential candidate if you are male or female between 18 and 60 and at least 12 weeks post injury.

- **Fourth**, there are dual endpoints -- not just safety but also effect on function.

**From SC, Inc. PR department:**

The Pathway Study is the first clinical trial designed to evaluate both the safety and efficacy of transplanting neural stem cells into patients with traumatic injury to the cervical spinal cord. The trial will be conducted as a randomized, controlled, single-blind study and efficacy will be primarily measured by assessing motor function according to the International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI).  The primary efficacy outcome will focus on change in upper extremity strength as measured in the hands, arms, and shoulders. The trial will follow the participants for one year and will enroll approximately 52 subjects.

The Company completed enrollment in the open-label Phase I/II study in thoracic SCI earlier this year and has reported interim results on all twelve subjects each having at least six months of follow-up post transplantation. Post-transplant gains in sensory function below the level of injury were demonstrated in half of the subjects. Two subjects converted from a complete injury to an incomplete injury and it has been further observed that one subject with an incomplete injury has shown signs of voluntary toe movement.  The interim results also continue to confirm the favorable safety profile of the cells and the surgical procedure.

Two patients from the Phase I/II study, featured in [videos](http://www.stemcellsinc.com/News-Events/Video-Library.htm) on the StemCells, Inc. internet site, reported gains in sensation.

We have followed StemCells Inc. over the years, going back to November 2010  when the company first announced its Swiss-based trial. The basic pre-clinical research for the company’s human stem line used in theses studies originated in the labs of[Aileen Anderson and Brian Cummings,](http://www.spinalcordinjury-paralysis.org/blogs/18/266) a husband-wife team at UC Irvine. The work was published in 2005. Anderson is a member of the Reeve Foundation’s International Consortium on Spinal Cord Injury.

Not everyone enrolled will get the stem cell surgery. Those who don’t get cells will be controls, used for comparing effect. Here’s how the company breaks it down:

Eligible patients who agree to participate will be assigned to one of three groups:

**Group 1**: These patients will undergo surgery and receive HuCNS-SC cells. Group 1 is open to both AIS A and B patients.

**Group 2**: These patients will be randomly assigned to either undergo surgery or to participate as a control patient. Control patients will not receive HuCNS-SC cells. Half of the patients will be assigned to surgery and the other half will be in the control group. Group 2 is open to both AIS A and B patients.

**Group 3**: These patients will undergo surgery and receive HuCNS-SC. Group 3 is open only to AIS C patients.

Patients who do not undergo surgery are equally as important in the study as those who undergo surgery. The study cannot achieve its goals without the support and cooperation of all patients, including control patients. Having control patients is a critical part of clinical research studies and allows researchers to measure differences between the groups.

**Patients assigned to surgery**
Patients who are scheduled for surgery will be given medications to suppress their immune systems. These medications may help prevent the immune system from rejecting the transplanted cells. Patients undergoing surgery will also be evaluated by several different specialists prior to undergoing surgery.

Patients undergoing transplantation will remain in the hospital for additional tests and procedures until they have recovered enough to return home.

Patients who undergo transplantation will have five follow-up visits after the surgery. For up to a year after the surgery, these visits will take place every one to three months and will involve physical exams, blood tests, and MRI scans.

**Patients assigned to no surgery (control patients)**
Patients who do not undergo surgery will not be hospitalized. They will be seen routinely over the course of a year and undergo the same basic physical exams and MRIs as the patients who had surgery.

For those interested, please see the Pathway [website](http://www.sciresearchstudy.com/).  See also the trial listing at [ClinicalTrials.gov](http://http/clinicaltrials.gov/ct2/show/NCT02163876?term=stem%20cells%20cervical%20spinal%20cord%20injury&rank=1)

Posted by [Sam Maddox](http://www.spinalcordinjury-paralysis.org/profile/maddogz) on Dec 20, 2014 5:33 PM US/Eastern