**Stem Cells for Paralysis: First of Its Kind Study POSTED APRIL 03, 2015, 2:45 PM**

**HEALTH**

According to the Christopher and Dana Reeve Foundation, nearly one in 50 people is living with paralysis. Until now, there wasn’t much hope. But a new study involving stem cells has doctors and patients excited.

Two years ago, Brenda Guerra’s life changed forever.

Guerra told Ivanhoe, “They told me that I went into a ditch and was ejected out of the vehicle.”

The accident left the 26-year-old paralyzed from the waist down, and confined to a wheelchair.

“I don’t feel any of my lower body at all” she said.

Guerra has traveled from Kansas to UC San Diego to be the first patient to participate in a ground-breaking safety trial, testing stem cells for paralysis.

Joseph D. Ciacci, MD, Professor of Neurosurgery at UC San Diego told Ivanhoe, “We are directly injecting the stem cells into the spine.”

The stem cells come from fetal spinal cords. The idea is when they’re transplanted they will develop into new neurons and bridge the gap created by the injury by replacing severed or lost nerve connections. They did that in animals and doctors are hoping for similar results in humans. The ultimate goal is to help people like Brenda walk again.

“The ability to walk is obviously a big deal not only in quality of life issues, but it also affects your survival long-term” Dr. Ciacci said.

Guerra received her injection and will be followed for five long years. She knows it’s only a safety trial but she’s hoping for the best

Guerra explained, “I hope to get up and walk again. Any little change, any little hope is enough for all of us.”

This is the first study to inject neural stem cells into people with complete thoracic spinal cord injuries. Participants must have had their injury occur one to two years ago and have to have feeling in their upper bodies. Researchers will enroll four patients in the safety trial, and then they hope to move on to a larger phase of the study.

**BACKGROUND:**There are more than 250,000 Americans living with spinal cord injuries right now. The spinal cord is a bundle of nerves that carries signals between the brain and the rest of the body. When the spinal cord is damaged due to trauma, such as a car accident, the effects can be severely debilitating. The injury is most often caused by a fracture or dislocation to the vertebrae, the bones that encase the nerves of the spinal cord. There are two types of spinal cord injuries: complete or incomplete. Complete spinal cord injuries occur when the cord can’t send signals to areas of the body below the injury site. The effect of this is paralysis below the affected area. With an incomplete injury, the cord is still able to send some signals below the injury site. People with an incomplete injury are able to feel some sensation below the injury site. Symptoms of a spinal cord injury include extreme pain in the back or neck, loss of movement, loss of bowel or bladder control, numbness in the hands or feet, and exaggerated reflexes.

(Source:  [**http://www.nlm.nih.gov/medlineplus/spinalcordinjuries.html**](http://www.nlm.nih.gov/medlineplus/spinalcordinjuries.html),[**http://www.brainandspinalcord.org/spinal-cord-injury/statistics.htm**](http://www.brainandspinalcord.org/spinal-cord-injury/statistics.htm),[**http://www.mayoclinic.org/diseases-conditions/spinal-cord-injury/basics/symptoms/con-20023837**](http://www.mayoclinic.org/diseases-conditions/spinal-cord-injury/basics/symptoms/con-20023837) )

**TREATMENT:**Right now, spinal cord injuries are irreversible, so treatment focuses on preventing more damage and helping the patient regain independence.  Giving methylprednisolone to patients within eight hours of the injury can help with inflammation and reduces damage at the injury site. Surgery may also to stabilize the spinal cord and remove bone fragments. After the initial injury has stabilized, the patient will undergo rehabilitation to strengthen existing muscle function and redevelop motor skills.

(Source: [**http://www.mayoclinic.org/diseases-conditions/spinal-cord-injury/basics/treatment/con-20023837**](http://www.mayoclinic.org/diseases-conditions/spinal-cord-injury/basics/treatment/con-20023837) )

**NEW TECHNOLOGY:**Researchers at UC San Diego are challenging the idea that spinal cord injury is irreversible. The first in-human clinical trials are underway to see if stem cells can treat the injuries. “The theory behind it is the stem cells will provide cells that will differentiate into the types of cells that can bridge the gaps that are created by an injury,” said Joseph Ciacci, MD. Dr. Ciacci is a neurosurgeon working on the project. Doctors have seen improvements in animals using the same method. The safety trial will follow four patients for five years after the first injection, but Ciacci says the study could move out of safety trials in as soon as a year.

(Source: [**http://health.universityofcalifornia.edu/2014/10/20/stem-cell-science-takes-bold-step-at-uc-san-diego/**](http://health.universityofcalifornia.edu/2014/10/20/stem-cell-science-takes-bold-step-at-uc-san-diego/), Joseph Ciacci, MD, UC San Diego)

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**If this story or any other Ivanhoe story has impacted your life or prompted you or someone you know to seek or change treatments, please let us know by contacting Marjorie Bekaert Thomas atmthomas@ivanhoe.com**

*Joseph Ciacci, M.D., Neurosurgeon and Professor of Surgery at UCSD, talks about using neural stem cells to help paralysis patients.*

*Interview conducted by Ivanhoe Broadcast News in November 2014.*

**Why do you think stem cells will be able to help paralysis patients?**

**Dr. Ciacci:**It’s a sort of a hope more than a think. Stem cells differentiate in to the types of cells that can bridge the gaps that are created by an injury. The hope is to restore function so that patients can regain ambulation. The ability to walk is obviously a big deal not in quality of life issues but also survival long-term that you’d be able to be up and around and walk.

**Do you inject the stem cells into the spine?**

**Dr. Ciacci:** The study that we’re doing is a safety study because it’s the first time it has been done. We are directly injecting the stem cells into the spine to demonstrate that it can be done and be done safely. After we’ve demonstrated this, we need to prove that there is some beneficial sort of effect of the stem cells.

**What type of stem cells do you use?**

**Dr. Ciacci:**Human neural stem cells and spinal cord stem cells.

**Do you get it from donors? Is it like a transplant and then the person has to take transplant drugs?**

**Dr. Ciacci:**Right. There are a lot of components to that question. They’re a cell line that was derived from fetal spinal cord stem cells. It’s a single donor, not over and over donors. That cell line has been perpetuated in a lab. In each case, we’re using that same cell line. It is in a sense a transplant and right now we are using immunosuppression like you would in any type of transplant situation. It’s like an organ transplant. We’re establishing the parameters for that type of immunosuppression in this type of transplantation because even though it’s something that has been done for organ transplantation, it’s not really something that’s established for stem cell transplantation. There’s so many exciting sort of novel aspects to this study.

**A couple of years ago, you could literally roll across the border to Mexico in your wheelchair and get stem cells for paralysis in the hopes that maybe one would gain an inch of impact. How much healing will these patients gain? Could it be complete control of their legs again?**

**Dr. Ciacci:**One thing for sure that these patients are getting is the actual stem cells from a neural cell line. When a patient goes to other countries, it’s not quite clear what they’re actually getting. So, starting from that part of it, we’re certain in all of our cases that the patients are getting actual neural stem cells. All I can say is that we’ve had familization and improvement in animal studies that we’ve done with the same cells in spinal cord injury models. After we’ve demonstrated safety in the current study that we’re doing, we’re certainly going to try to do some outcome studies and demonstrate improvement. When you ask what type of improvement, because it’s novel any improvement would be worthwhile. Certainly, many patients would be happy with even a little bit of sensation or any type of voluntary control of even the smallest portion of their lower extremity. In the best case scenario, the thing that everybody hopes for is that people are going to walk who haven’t walked before. But, that’s a bit of a ways down the road.

**In your lab studies in animals, what were some of the findings?**

**Dr. Ciacci:**Animals have really specific sort of ways that we can test. They have the way they stand and the way they can move around. They don’t have as much of an ability for us to examine individual muscle groups, although there are electrophysiologic ways of testing that the transmissions are better. Mostly, it’s that they have more coordination and ability to do some of the normal activities that they do in their routine.

**What would be the protocol? How long until you start seeing something happen?**

**Dr. Ciacci:** The protocol is very specific in terms of what we do and what we’re trying to find out. We inject the cells and follow the patients for five years with multiple imaging studies and other examinations and electrophysiology. What we’re trying to demonstrate is that this is something that can be done without doing harm. At the same time, we are examining these patients and testing them. We may see some positive benefit although that’s not the purpose of this study. In terms of predicting how long it would take to see a positive benefit, it’s not been done and so it’s impossible for me to say. I’m hopeful that five years is long enough to find what we need but it could take longer.

**Why focus on neural stem cells?**

**Dr. Ciacci:**It’s a way of having consistency in the cell type that you’re using. It’s a cell line that’s been established over time as consistent. Because it’s a neural stem cell, a spinal cord stem cell doesn’t have to have that extra sort of task of becoming a spinal cord stem cell for a human.

**Is this the newest and only hope out there right now for people who want to walk again?**

**Dr. Ciacci:** It’s definitely the newest. I don’t say only hope because hope is really important and I like to have people have hope. There certainly are other things that should be investigated. But, it’s definitely new and definitely unique in that way.

**What excites you about this?**

**Dr. Ciacci:**Everything. I have years and years of tenderness that has developed for these patients. I have seen so many young, healthy people who are very active end up in a situation where they can’t do a lot of the things that most of us take for granted and really become dependent upon others. I see how it can be devastating for the families and everyone else around them when they feel like there’s no hope, that this is sort of their permanent condition. We’ve gotten really good at keeping people alive a really long time like this. So, to be able to offer an opportunity for them to regain independence and ability to resume normal activities, or at least some of the activities that made them the person they were, really does excite me.

**How soon could we see this move out of safety trials?**

**Dr. Ciacci:**It could be very soon. It could be as soon as a year, maybe a little longer than that assuming that all goes very well with what we’re doing.

**Is there any risk?**

**Dr. Ciacci:**There is no surgery without risk. The surgery itself, independent of the stem cells, carries risk but we’ve gotten pretty good at mitigating that and have a lot of experience with the spinal cord injury patients. The stem part itself has some risks again because it’s an unknown. There’s a risk of infection that comes with the immunosuppression that we’ve discussed. There’s a risk that these stem cells could potentially grow and differentiate into things that one wouldn’t want in this area. There’s also a risk of malignancy. These are small risks and we’re very careful about it.

**Is this only for a certain type of paralysis?**

**Dr. Ciacci:**This is a specific study for chronic, meaning one to two years post thoracic spinal cord injury. So, that would be legs only. Arms would be intact.

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