

Herzlich  
Willkommen

XCell-Center

Institute for Regenerative Medicine

# SCI

## Spinal Cord Injury

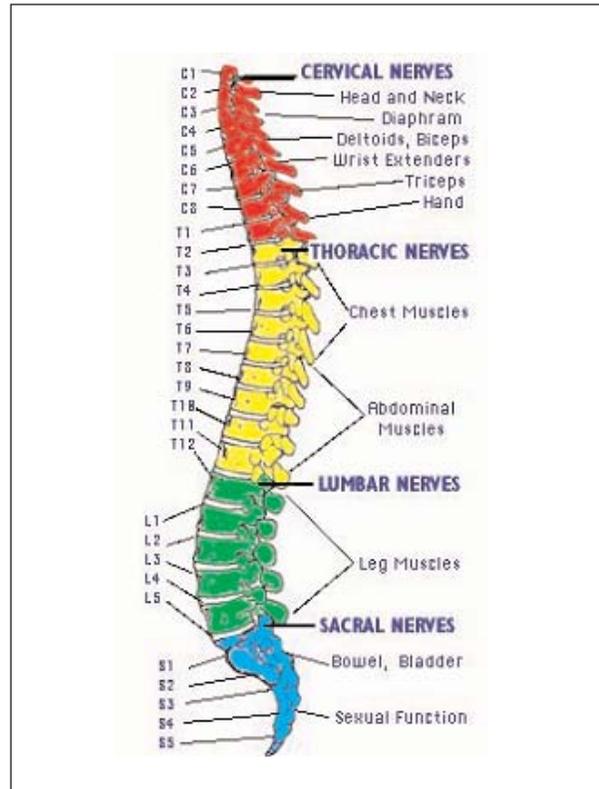
## Information for patients

SCI treatment with autologous adult stem cells from your own bone marrow

## Spinal Cord Injury (SCI)

A spinal cord injury usually begins with a sudden, traumatic blow to the spine that fractures or dislocates vertebrae. The damage begins at the moment of injury when displaced bone fragments, disc material, or ligaments bruise or tear into spinal cord tissue. Most injuries to the spinal cord don't completely sever it. Instead, an injury is more likely to cause fractures and compression of the vertebrae, which then crush and destroy the axons, extensions of nerve cells that carry signals up and down the spinal cord between the brain and the rest of the body. An injury to the spinal cord can damage a few, many, or almost all of these axons. Some injuries will allow almost complete recovery. Others will result in complete paralysis.

Spinal cord injuries are classified as either complete or incomplete. An incomplete injury means that the ability of the spinal cord to convey messages to or from the brain is not completely lost. People with incomplete injuries retain some motor or sensory function below the injury. A complete injury is indicated by a total lack of sensory and motor function below the level of injury. People who survive a spinal cord injury will most likely



have medical complications such as chronic pain and bladder and bowel dysfunction, along with an increased susceptibility to respiratory and heart problems. Successful recovery depends upon how well these chronic conditions are handled day to day.

### Treatment

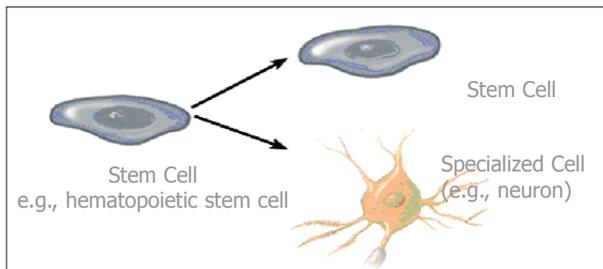
Improved emergency care for people with spinal cord injuries and aggressive treatment and rehabilitation can minimize damage to the nervous system and even restore limited abilities. Respiratory complications are often an indication of the severity of spinal cord injury. About one-third of those with injury to the neck area will need help with breathing and require respiratory support. The steroid drug methylprednisolone appears to reduce the damage to nerve cells if it is given within the first 8 hours after injury. Rehabilitation programs combine physical therapies with skill-building activities and counseling to provide social and emotional support.

Besides these kinds of treatments, stem cell therapy can be used to restore sensory and motor functions.

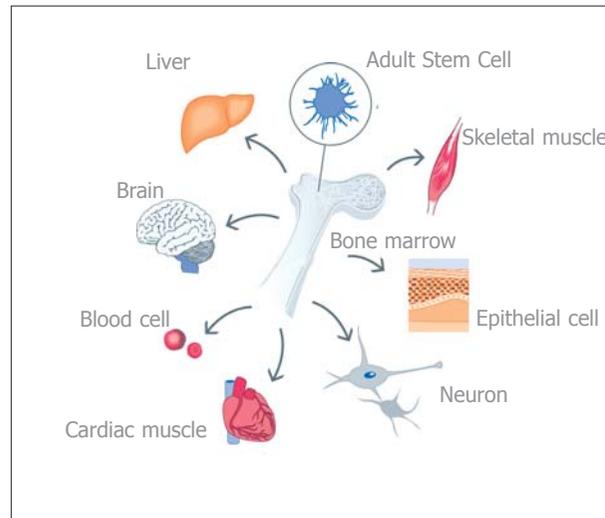
## About Stem Cells

The discovery of the stem cell has led to a revolution in modern medicine. Stem cells are in fact, the "smart cells" of our bodies. These cells migrate to injured areas within the body and transform themselves into new tissue cells that replace the damaged ones. The body repairs itself by continuously producing new cells and tissues in this manner.

Stem cells have the capacity to multiply and to renew themselves almost indefinitely. This contrasts with nerve cells, muscle cells and blood cells, which cannot multiply themselves and have limited life spans. Stem cells can also develop into specialized cells.



Stem cells from the bone marrow can develop into cardiac muscle, as well as liver, brain, nerve, fat and skin tissue. Examples of bone marrow-derived stem cell development are illustrated above. In SCI patients these stem cells can grow into nerve tissue, new blood vessels that improve circulation, or produce stimulants that activate non-active cells.



## The XCell-Center SCI Treatment

The entire procedure consists of the following phases: eligibility, stem cell collection and processing, stem cell treatment, and follow-up.

### Objectives

The goal of this treatment is to repair damaged tissue or to reactivate existing cells, thus recovering, as much as possible, functions lost as a result of the injury.

### Type of treatment

The XCell-SCI procedure employs autologous adult stem cells. These cells are collected from your own bone marrow. A few days prior to treatment, the stem cells will be isolated from bone marrow taken from your hip (iliac crest).

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## Eligibility Phase

SCI diagnosis based on your medical history, imaging material such as MRI or CT scan, radiology report and neurological report.

- The XCell-Center medical team approves you for treatment.

These pictures show the Bone Marrow Collection Procedure



*Arrival at XCell-Center*



*Preparation*



*Application of local anesthetic*



*Disinfection of the collection site*



*Needle insertion into the hip bone (iliac crest)*



*Sample collection*

- Your bone marrow contains a sufficient quantity of viable stem cells. This is assessed during the processing phase.

### Stem Cell Collection and Processing

Prior to scheduling bone marrow collection, you will be asked to fill out the patient consent form. This form grants explicit written permission for bone marrow collection.

You must discontinue using any blood diluting medications at least 10 days before your collection date. You should consult your physician before discontinuing the use of blood diluting drugs.

When we greet you on collection day, we'll have everything prepared to begin collection and make it comfortable for you.

Your physician will collect approximately 150 - 200 ml of bone marrow from your hip bone.

Stem cell collection is performed as an out-patient procedure under local anesthesia in sterile conditions. It is comparable in pain to a dentist visit. During the collection, you will barely feel the needle insertion into your hip bone. Afterwards, the collection site might look like a "blue spot" and be a bit painful for 3 - 4 days. Normally, there are no other side-effects. Theoretically, there is a small risk of infection. We minimize this risk by working in a sterile environment.

Within 48 hours, the stem cell samples are processed and quality tested by a highly specialized laboratory in totally sterile, clean room conditions. Since they are in sterile tubes and never come into contact with the air, these samples cannot be contaminated.

Bone marrow processing and quality testing consists of:

- Stem cell isolation - stem cells are separated from the red blood cells and blood plasma.
- Stem cell counting and vitality measurement.



**Stem cell processing results are documented in an analysis report.**

The result is positive if:

- There are more than two million (2,000,000) CD34<sup>+</sup> stem cells present.
- The CD34<sup>+</sup> stem cells have a vitality greater than 80%

Positive isolated stem cell samples are stored in sterile tubes at minus 196°C in liquid nitrogen.

### Stem Cell Implantation

Your high-quality stem cell sample can be implanted two ways: intrathecal injection (into spinal canal) and direct implantation (surgery). Each method has distinct advantages and disadvantages.

#### 1. Intrathecal Injection

Under a local anesthetic, your stem cells (in a volume of 4ml) will be injected directly into the cerebrospinal fluid via lumbar puncture. Since the cerebrospinal fluid circulates, stem cells are transported directly to the damaged tissue in the brain or the spinal cord. The entire procedure usually takes about 30 minutes.

Immediately after treatment, you will spend about three or four hours laying in bed in our recovery room for observation. As with any minimally invasive intervention, intrathecal stem cell implantation carries a very small risk of infection. We minimize this risk by working in a sterile

environment and by prescribing prophylactic antibiotics to you. If there are no complications, you can return home or to your hotel.

#### Possible Adverse Events from the treatment

After the procedure, you might experience the following adverse events. These events can be intense but usually subside within two or three days.

- Nausea
- Headache
- Backache and/or Leg pain



#### Treatment advantages:

- Simple
- Out patient
- Less invasive than surgery
- Lower cost than surgery

#### Treatment disadvantages:

- Less precise application

#### Follow-up

Once you have returned home, a member of our medical team will regularly monitor your progress via telephone and email. For your convenience, a telephone 'hotline' is always at your disposal.

#### Cost

The price for the intrathecal treatment is 6,545 Euros. This price includes:

- Bone marrow collection and transportation
- Stem cell processing, storage and transportation

- Stem cell administration
- XCell-Center medical fees
- XCell-Center administrative fees

This price **does not include travel expenses** such as airfares, meals and hotel accommodations.



## 2. Direct Implantation (Surgery)

The highest precision targeting of stem cells is achieved with direct surgery. The stem cells are implanted using microinjections directly into the point of injury. This procedure takes about three hours and is performed under general anesthesia.

Immediately after the procedure, nurses will closely monitor you in the recovery room. Normally, you will be discharged from the hospital after three or four days.

### Possible Adverse Effects from the treatment

- Reaction to anesthetic: nausea and headache
- Infection - risk minimized by prescribing prophylactic antibiotics to each patient
- Unintended spinal cord damage
- Wound healing problems

### Treatment advantages

- Highly precise application increases success rate

### Treatment disadvantages

- More invasive than intrathecal procedure
- Hospital stay is required
- More expensive than intrathecal procedure

### Follow-up

Once you have returned home, a member of our medical team will regularly monitor your progress via telephone and email. For your convenience, a telephone 'hotline' is always at your disposal.

### Cost

The total price for the surgical treatment is 19,635 Euros. This price includes:

- Bone marrow collection and transportation
- Stem cell processing, storage and transportation
- Stem cell administration
- XCell-Center medical fees

- XCell-Center administrative fees
- Hospital room for the patient, plus hotel room for one companion; maximum four days (*Direct implantation only*)

This price **does not include travel expenses** such as airfares and meals, or accommodation costs after day four.

### General

No additional charges will be incurred unless you are required to extend your stay at the medical center as a result of complications. Costs do not include additional stem cell treatments. If another treatment is necessary, we will discuss potential options with you.

You will receive an invoice one week prior to treatment. This invoice must be paid in-full before treatment can begin.

**Note:** If your bone marrow sample is negative or the stem cells cannot be administered due to unforeseen medical circumstances, you will only be required to pay charges incurred to that point. In the case of a negative bone marrow sample, it might be possible to schedule another bone marrow collection.

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