

# STEM CELL CLINICAL TRIAL: Adipose Stem Cells for Traumatic Spinal Cord Injury

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## BACKGROUND:

- Spinal Cord Injury (SCI) is a devastating prognosis with very little pharmacological treatments to improve function.
- One of the most challenging aspects of this life altering condition is its complex pathophysiology following the primary injury. Changes in the microenvironment cause the spinal cord to be left in a refractory state. Due to the multidimensional complexity of SCI, cell-based therapies are a source of potential treatment.
- Stem cells have the ability to modulate the microenvironment by influencing the inflammatory response and secreting growth factors.
- Adipose tissue derived Mesenchymal stem cells (AD-MSCs) are a readily accessible cell source with high proliferative capacity making them excellent candidates for cellular therapies, including the treatment of SCI.

## METHOD:

- The study presents results for the first patient enrolled in this phase 1 clinical trial using autologous AD-MSCs for the treatment of paralysis due to traumatic SCI.
- The patient was a 53 year old male with a SCI at C3-4 resulting in complete loss of motor and sensory function below the injury site. The patient underwent a posterior cervical decompression and fusion surgery with improvements being observed postoperatively. However, after 6 months advancements in neurological function plateaued. The patient was enrolled in the clinical trial 9 months post injury.
- Adipose tissue was biopsied from the abdominal wall with MSCs being isolated from the tissue, expanded, and cryopreserved.
- The patient then received 100 million cells via an intrathecal injection at L3-4 at 11 months post injury and 5 months following the plateau in improvements. Neurological status of the patient was assessed at days 2 and 3 following treatment, and weeks, 1, 2, 4, 12, 24, 48, and 72.

## RESULTS:

- The patient reported no severe adverse effects for the duration of the 18 month study.
- Improvements were recorded in the following: ASIA upper extremity and lower extremity motor scores, ASIA sensory pinprick and light touch scores, as well as notable improvements in ability to push and pull with arms and use hands and fingers.
- In addition, a substantial improvement in the quality of life of the patient was also observed using the Global Health Score. Improvements were also observed in physical therapy and occupational therapy with reduction in time and an increase in speed being recorded for the 10 meter walk.
- At baseline the patient was recorded a time of 57.72 seconds at 0.17 m/s. At 15 months his time improved to 23.00 seconds at 0.43 m/s with substantial improvement in ambulation. In addition, at baseline the patient was only able to walk a distance of 635 feet for 12.8 seconds, this improved to 2200 feet for 34 minutes following cellular therapy. Lastly an increase in range of motion was also observed, with specific improvement being noted in shoulder flexion.

## CONCLUSION:

- Intrathecal AD-MSC administration may offer a noninvasive and safe therapy for the treatment of SCI with the potential to improve neurological function in patients who have reached a plateau in clinical improvements.

## ASSOCIATED PUBLICATIONS:

- <https://clinicaltrials.gov/ct2/bye/rQoPWwoRrXS9-i-wudNgpQDxudhWudNzlXNiZip9Ei7ym67VZRFj-K48ORFjA6h9Ei4L3BUgWwNG0it>