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STEM CELL CLINICAL TRIAL:

Safety Study of Local Administration of Autologous Bone Marrow Stromal Cells in Chronic Paraplegia

NCT01909154

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BACKGROUND:

- **Spinal Cord Injury (SCI) is a devastating diagnosis with no cure or effective form of treatment to date.**
- **The present standard of care is methylprednisone and/or decompression, with neither preventing or changing the pathological decent brought on by SCI.**
- **In addition, the complexity of the trauma magnifies the need for a cellular based therapy.**
- **The expanding field of research in adult stem cells has resulted in possible alternative treatments for many disorders to include those of the spinal cord.**
- **The objective of this study was to determine if multiple route administration of bone marrow derived stem cells (BMSCs) was a safe and feasible treatment for SCI.**

METHOD:

- Criteria for the study included that participants have a spinal cord injury with paraplegia or paraparesia; be able to undergo an MRI; be over the age of 13; and have a desire to engage in the study.
- Candidates with depression, psychosis, or any mental disorder were excluded. Other excluding factors were alcohol and drug abuse, other disease or blood related disorders; multiple acute injuries; and patients with a life expectancy of less than 2 years.
- On admittance to the trial participants underwent an extensive medical exam to include magnetic resonance imaging (MRI) as well as psychological and neurological exams.

METHOD: CONTINUED

- Bone marrow was harvested from the iliac crest, 100 mL total, with 5 mL aspirations being collected at 10 sites on the left and 10 sites on the right.
- The mononuclear cells were then isolated using centrifugation, washed with sterile saline and prepared for fluorescence activated cell sorting (FACS) analysis.
- Prior to injection, mononuclear cels were resuspended in saline and autologous plasma at a total volume of 80 mL.
- The total number of mononuclear cells obtained for transplant was 400 million.

- Scar tissue was first carefully removed. Using a 21 gauge needle, 1 mL injections of the cell suspension were performed in and around the site of injury as well as in any intraspinal cavities for a total of 20 mL.
- An additional 30 mL was administered into the spinal canal and the remaining 30 mL was delivered intravenously for a total of 80 mL.
- A multiple route administration was used to ensure that BMSCs had the potential to reach their appropriate target.
- Follow up testing was performed at 6 months, 1 year, and 2 years following administration.

RESULTS:

- **The ASIA Impairment Scale, Frankel Scale and Modified Ashworth score were used to measure spasticity changes following cell transplantation.**
- **Data indicated improvement for motor scores in all cases as well as improvements in sensory light touch and pin prick scores. The Barthel Index as well as a novel measurement for bladder control were used to document changes in quality of life.**
- **Barthel scores indicated an improvement in the quality of life, with the greatest improvements occurring at 6 months post BMSC treatment.**
- **Overall all SCI cases evaluated resulted in improved bladder function. MRI performed at 6 months, 1 year, and 2 years post treatment indicated that the multiple route administration of BMSCs may lead to morphological changes in the spinal cord.**
- **The study resulted in no cases of tumor formation, infection or increased pain, and very few instances of minor adverse effects.**

CONCLUSION:

- Multiple route administration of BMSCs is a feasible and safe form of treatment for SCI. Most importantly it has been documented to improve the quality of life for those suffering from such a debilitating disorder with no incidence of severe adverse reactions.

ASSOCIATED PUBLICATIONS:

- https://clinicaltrials.gov/ct2/bye/rQoPWwoRrXS9-i-wudNgpQDxudhWudNzlXNiZip9Ei7ym67VZRC5Fg0VEg0BA6h9Ei4L3BUgWwNG0it.