

ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 09/15/2015

Safety and Feasibility Study of Cell Therapy in Treatment of Spinal Cord Injury

This study is currently recruiting participants.
Verified by Translational Biosciences, September 2015

Sponsor:	Translational Biosciences
Collaborators:	
Information provided by (Responsible Party):	Translational Biosciences
ClinicalTrials.gov Identifier:	NCT02237547

Purpose

Human Umbilical Cord-derived Mesenchymal Stem Cells (UC-MSC) and Bone Marrow Mononuclear Cells (BMMC) from the patient injected into the spinal fluid intrathecally and injected intravenously (IV) is a safe and therapeutic procedure for spinal cord injury (SCI) patients.

Condition	Intervention	Phase
Spinal Cord Injury	Biological/Vaccine: Intravenous and intrathecal human umbilical cord tissue-derived mesenchymal stem cells and bone marrow mononuclear cells	Phase 1/ Phase 2

Study Type: Interventional

Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study

Official Title: Safety and Feasibility Study of Cell Therapy in Treatment of Spinal Cord Injury

Further study details as provided by Translational Biosciences:

Primary Outcome Measure:

- Number of patients with adverse events [Time Frame: 12 weeks, 52 weeks] [Designated as safety issue: Yes]
12 and 52 weeks after final treatment

Secondary Outcome Measures:

- Number of subjects with a change in American Spinal Injury Association (ASIA) score from baseline [Time Frame: 12 weeks, 52 weeks] [Designated as safety issue: No]
12 and 52 weeks after final treatment
- Number of subjects with a change in Frankel Scale score from baseline [Time Frame: 12 weeks, 52 weeks] [Designated as safety issue: No]
12 and 52 weeks from final treatment

Estimated Enrollment: 20

Study Start Date: September 2014

Estimated Primary Completion Date: September 2016

Estimated Study Completion Date: March 2018

Arms	Assigned Interventions
Experimental: IV and IT UC-MSC and BMMC Intravenous and intrathecal human umbilical cord tissue-derived mesenchymal stem cells and bone marrow mononuclear cells	Biological/Vaccine: Intravenous and intrathecal human umbilical cord tissue-derived mesenchymal stem cells and bone marrow mononuclear cells

Detailed Description:

The proposed study will assess primary safety and secondary efficacy endpoints of autologous bone marrow mononuclear cells and allogeneic human umbilical cord-derived mesenchymal stem cells administered to 20 male and female subjects between ages of 18-50 with spinal cord injury. These cells will be administered intrathecally and intravenously multiple times over the course of one month.

The primary objective is freedom from treatment-associated adverse events at 3 and 12 months post-treatment. Secondary objective will be efficacy at baseline, 3 months and 12 months and will be quantified based on the following: American Spinal Cord Injury Association (ASIA) classification and the Frankel Scale.

Eligibility

Ages Eligible for Study: 18 Years to 50 Years

Genders Eligible for Study: Both

Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Men and women between age 18 and 50
- Paraplegics and quadriplegics with complete or incomplete spinal cord injuries.
- Willingness to undergo bone marrow derived autologous cell therapy.
- Ability and willingness to make regular visits to hospital and follow ups during the protocol procedure and comply with all medical instructions
- Traumatic Injury of spinal cord with complete or partial damage by Magnetic Resonance Imaging (MRI) and injury level below C4
- ASIA impairment scale from A – C
- Must have proof of health insurance in country of residence.
- Signed informed consent

Exclusion Criteria:

- Pre- existing or current systemic disease such as lung, liver (exception: history of uncomplicated hepatitis A), gastrointestinal, cardiac, Human Immunodeficiency Virus (HIV)
- History of life threatening allergic- or immune-mediated reaction
- Hemodynamic instability
- Peripheral muscular dystrophy
- Lactating or pregnant woman
- Women capable of childbearing unwilling to use multiple forms of contraception
- Alcohol drug abuse /dependence
- Positive test result for hepatitis A and Hepatitis B OR C
- Major-traumatic brain injury and psychiatric illness
- Open injuries
- Active infectious diseases
- Life expectancy of less than one year due to terminal condition
- Neurodegenerative diseases
- Primary hematologic diseases

- Any of the following medications that cannot be discontinued one week prior to the first stem cell administration and throughout the course of treatment. (1 week before visit 2 through one week after visit 12)
 - Antibiotics
 - Antifungals
 - Antivirals
 - Blood thinners (to avoid bleeding risk during bone marrow aspiration and IT procedures)
 - High doses of Vitamin D or fish oils (since these might prolong bleeding times)
- Bone reflecting increased risk for spinal puncture
- Hepatic dysfunction
- Other medical complications that contraindicate surgery, including major respiratory complications
- Participation in another clinical trial
- Coagulopathies
- Uncorrected coagulopathy during the baseline period defined as: International Normalized Ratio (INR) > 1.4; Partial Thromboplastin Time (PTT) > 35 sec; Platelet Count (PLT) < 100,000.
- Pre-injury history of seizure disorder and/or neurological impairment where participation in age-appropriate pain rating scales would not be practical or possible
- Subject does not sign informed consent form

Contacts and Locations

Locations

Panama

Stem Cell Institute Recruiting

Panama City, Panama

Contact: Laysa Adames (817) 945-9228 trials@translationalbiosciences.com

Sub-Investigator: Jorge Paz-Rodriguez, MD

Investigators

Principal Investigator: Nelson Novarro, MD Unaffiliated

More Information

Responsible Party: Translational Biosciences

Study ID Numbers: CNEI-2014-TBS-UCMSC-SCI001

Health Authority: Panama: Ministry of Health

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services