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

This study is currently recruiting participants. (see Contacts and Locations)

Verified September 2014 by Translational Biosciences

Sponsor:
Translational Biosciences

Information provided by (Responsible Party):
Translational Biosciences

ClinicalTrials.gov Identifier:
NCT02237547

First received: September 9, 2014
Last updated: NA
Last verified: September 2014
History: No changes posted

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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: 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: Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

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

Resource links provided by NLM:

MedlinePlus related topics: Spinal Cord Injuries

U.S. FDA Resources

Further study details as provided by Translational Biosciences:

Primary Outcome Measures:

- 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 Study Completion Date: March 2018
Estimated Primary Completion Date: September 2016 (Final data collection date for primary outcome measure)

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: 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

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02237547

Locations

Panama

Stem Cell Institute — **Recruiting**
Panama City, Panama
Contact: Marggie Arosemena +507 306-2612 (Panama) trials@translationalbiosciences.com
Sub-Investigator: Jorge Paz-Rodriguez, MD

Sponsors and Collaborators

Translational Biosciences

Investigators

Principal Investigator: Nelson Novarro, MD

More Information

No publications provided

Responsible Party:	Translational Biosciences
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Health Authority:	Panama: Ministry of Health

Keywords provided by Translational Biosciences:

spinal cord injury	mononuclear cells
mesenchymal	stem cells
bone marrow	umbilical cord

Additional relevant MeSH terms:

Spinal Cord Injuries	Nervous System Diseases
Spinal Cord Diseases	Trauma, Nervous System
Central Nervous System Diseases	Wounds and Injuries

ClinicalTrials.gov processed this record on September 18, 2014

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