ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
Release Date: 12/18/2014

Feasibility Study of Human Umbilical Cord Tissue-Derived Mesenchymal Stem Cells in Patients With Multiple Sclerosis

This study is ongoing, but not recruiting participants.

Sponsor:	Translational Biosciences
Collaborators:	
Information provided by (Responsible Party):	Translational Biosciences
ClinicalTrials.gov Identifier:	NCT02034188

Purpose

Allogeneic human umbilical cord tissue-derived stem cells injected intravenously (IV) once per day for 7 days is a safe and will induce a therapeutic effect in multiple sclerosis (MS) patients.

Condition	Intervention	Phase
Multiple Sclerosis	Biological/Vaccine: Umbilical cord mesenchymal stem cells	Phase 1/ Phase 2

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, N/A, Safety/Efficacy Study
Official Title: Phase 1//2 Study of Human Umbilical Cord Tissue-Derived Mesenchymal Stem Cells in Patients With Multiple Sclerosis

Further study details as provided by Translational Biosciences:

Primary Outcome Measure:

- Number of participants with adverse events [Time Frame: 12 months] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Number of participants with a change in disability as measured by Expanded Disability Status Scale (EDSS) [Time Frame: 12 months] [Designated as safety issue: No]
- Number of participants with a change in neurological impairment as measured by Scripps Neurological Rating Scale [Time Frame: 12 months] [Designated as safety issue: No]
- Number of participants with a change in cognitive function as measured by the • Paced Auditory Serial Addition Test (PASAT) [Time Frame: 12 months] [Designated as safety issue: No]
- Number of participants with a change in upper extremity function as measured by the Nine Hole Peg Test [Time Frame: 12 months] [Designated as safety issue: No]
- Number of participants with a change in mobility and leg function as measured by the 25 foot walking test [Time Frame: 12 months] [Designated as safety issue: No]
- Number of participants with a change in quality of life as measured by the Short form 36 (SF-36) quality of life questionnaire [Time Frame: 12 months] [Designated as safety issue: No]

- Number of participants experiencing pulmonary edema as measured by 12-lead electrocardiogram (ECG) [Time Frame: 1 month, 3 months] [Designated as safety issue: Yes]
- Number of participants with a change in brain or spinal cord lesions as measured by gadolinium-enhanced magnetic resonance imaging (MRI) [Time Frame: 12 months] [Designated as safety issue: Yes]

Estimated Enrollment: 20
Study Start Date: January 2014
Estimated Primary Completion Date: February 2016
Estimated Study Completion Date: August 2017

Arms	Assigned Interventions
Experimental: Umbilical cord mesenchymal stem cells	Biological/Vaccine: Umbilical cord mesenchymal stem cells

Detailed Description:

The proposed study will assess primarily safety and secondary efficacy endpoints of allogeneic umbilical cord mesenchymal stem cells (UC-MSC) administered to 20 patients with MS.

The primary objective of the trial is freedom from treatment associated adverse events at 4,12 and 52 weeks post treatment. Secondary objective will be efficacy as assessed at baseline, week 12 and 52 and will be quantified based on the following: Neurological assessment of the MS functional composite assessment which comprises of Expanded Disability Status Scale (EDSS), the expanded EDSS (Rating Neurologic Impairment in Multiple Sclerosis, the Scripps neurological rating scale (NRS), paced auditory serial addition test (PASAT), the nine-hole peg test, and 25-foot walking time. Short-form 36 (SF-36) quality of life questionnaire and gadolinium enhanced MRI scans of the brain and cervical spinal cord will also be performed at the indicated time points.

Eligibility

Ages Eligible for Study: 18 Years to 55 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Patients willing to sign informed consent and capable of understanding the features of this clinical trial.
- Willing to keep a weekly diary and undergo observation for 12 months
- Non-pregnant patients 18-55 years of age with MS according to the revised McDonald criteria and meeting the Poser criteria for clinically defined MS.
- EDSS scores of 2·0 to 5·5 points assessed at least 3 months after the last acute attack of MS.
- Must have proof of health insurance in country of residence.

Exclusion Criteria:

- Patients with evidence of active proliferative retinopathy.
- Patients with poorly controlled diabetes mellitus (glycated hemoglobin: HbA1C > 8.5%).
- Patients with renal insufficiency (Creatinine> 2.5) or failure.
- Infection as evidenced by white blood cell (WBC) count of >15,000 k/cumm and/or temperature > 38 Celsius.
- History of organ transplant.
- History of previous or active malignancy, except for localised cutaneous basal or squamous cell carcinoma or carcinoma in situ of the cervix
- Exercise limiting angina (Canadian Cardiovascular Society Class 3
- Congestive heart failure (New York Heart Association class 3
- Unstable angina
- Acute ST elevation myocardial infarction (MI) within 1month
- Transient ischemic heart attack or stroke within 1 month
- Severe valvular heart disease

Contacts and Locations

Locations

Panama

Stem Cell Institute

Panama City, Panama

Investigators

Principal Investigator:	Jorge Paz-Rodriguez, MD	Translational Biosciences / Stem Cell Institute

More Information

Responsible Party:	Translational Biosciences
Study ID Numbers:	TBS-UCMSC-001
Health Authority:	Panama: Ministry of Health