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

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

Verified January 2014 by Translational Biosciences

Sponsor:
Translational Biosciences

Information provided by (Responsible Party):
Translational Biosciences

ClinicalTrials.gov Identifier:
NCT02034188

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

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: Umbilical cord mesenchymal stem 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: Phase 1//2 Study of Human Umbilical Cord Tissue-Derived Mesenchymal Stem Cells in Patients With Multiple Sclerosis

Resource links provided by NLM:

Genetics Home Reference related topics: multiple sclerosis

MedlinePlus related topics: Multiple Sclerosis

U.S. FDA Resources

Further study details as provided by Translational Biosciences:

Primary Outcome Measures:

- 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 Study Completion Date:	August 2017
Estimated Primary Completion Date:	February 2016 (Final data collection date for primary outcome measure)

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

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: NCT02034188

Locations

Panama

Stem Cell Institute **Recruiting**
Panama City, Panama
Contact: Aileen Batista +507 306-2633 trials@translationalbiosciences.com
Principal Investigator: Jorge Paz-Rodriguez, MS

Sponsors and Collaborators

Translational Biosciences

Investigators

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

More Information

No publications provided

Responsible Party:	Translational Biosciences
ClinicalTrials.gov Identifier:	NCT02034188 History of Changes
Other Study ID Numbers:	TBS-UCMSC-001
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Last Updated:	January 9, 2014
Health Authority:	Panama: Ministry of Health

Keywords provided by Translational Biosciences:
multiple sclerosis
umbilical cord
mesenchymal
stem cells

Additional relevant MeSH terms:

Multiple Sclerosis	Demyelinating Diseases
Sclerosis	Autoimmune Diseases
Demyelinating Autoimmune Diseases, CNS	Immune System Diseases
Autoimmune Diseases of the Nervous System	Pathologic Processes
Nervous System Diseases	

ClinicalTrials.gov processed this record on May 26, 2014

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