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

Umbilical Cord Tissue-derived Mesenchymal Stem Cells for Rheumatoid Arthritis

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:	NCT01985464

Purpose

Allogeneic human umbilical cord tissue-derived stem cells will be injected intravenously once per day for 5 days is a safe and useful procedure in inducing remission of RA in patients resistant to standard DMARD therapy.

Condition	Intervention	Phase
Rheumatoid Arthritis	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: Feasibility Study of Umbilical Cord Tissue Derived Mesenchymal Stem Cells (UC-MSC) in Disease Modifying Anti-Rheumatic Drugs (DMARD) Resistant Rheumatoid Arthritis

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 disease activity index as measured by 28-DAS Score [Time Frame: 12 months] [Designated as safety issue: No]
- Number of participants with a change in current disease activity as measured by EULAR Response Criteria [Time Frame: 12 months] [Designated as safety issue: No]
- Change from baseline quality of life measure (based on Stanford HAQ) [Time Frame: 12 months] [Designated as safety issue: No]
- Change from baseline C-reactive protein [Time Frame: 12 months] [Designated as safety issue: No]
- Change from baseline erythrocyte sedimentation rate (ESR) [Time Frame: 12 months] [Designated as safety issue: No]
- Change from baseline anti-citrulline antibody measure [Time Frame: 12 months] [Designated as safety issue: No]
- Change from baseline rheumatoid factor (RF) [Time Frame: 12 months] [Designated as safety issue: No]

Estimated Enrollment: 20

Study Start Date: October 2013
Estimated Primary Completion Date: December 2015
Estimated Study Completion Date: June 2016

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 UC-MSC administered to 20 patients with disease modifying antirheumatic drug (DMARD)-resistant Rheumatoid Arthritis (RA) who have been non-responsive to at least one course of one DMARD selected from a group comprising of: gold salts, leflunomide, methotrexate, and hydroxychloroquine.

The primary objective of safety will be defined as freedom from treatment associated adverse events for the period of one year. The secondary objective of efficacy will include evaluation at baseline and at months 3 and 12 of efficacy endpoints of C reactive protein (CRP), erythrocyte sedimentation rate (ESR), anti-citrulline antibody, rheumatoid factor (RF), Quality of Life Questionnaire, 28-joint disease activity score (DAS28), European League against Rheumatism (EULAR) response criteria and immunological parameters.

Eligibility

Ages Eligible for Study: 18 Years to 80 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- Age older than 18 years and ability to understand the planned treatment.
- Patients of either gender with RA with a duration of 6 to 72 months defined as the presence of at least three of the following criteria: 6 or more painful, 2 or more swollen joints, morning stiffness for at least 45 minutes (on average during the week prior to entry), and an erythrocyte sedimentation rate (ESR) of at least 28 mm.
- Non-responsive to at least one course of one DMARD selected from the group comprising of: gold salts, leflunomide, methotrexate, and hydroxychloroquine.
- Second-line agents are discontinued at least 4 weeks prior to entry.
- Able to tolerate ALL study procedures
- Able to give informed Consent
- Negative for human chorionic gonadotropin (HcG) with a serum pregnancy test
- Hematocrit ≥ 28.0%, White Blood Cell count ≤ 14,000, Platelet count ≥ 50,000,
- Life expectancy of 6 months or more in the opinion of the investigator
- Serum bilirubin, alanine aminotransferase/aspartate aminotransferase up to 2.5 time the upper level of normal.
- Controlled blood pressure (systolic blood pressure ≤140 and a diastolic blood pressure of ≤90 mmHG) and established anti-hypertensive therapy as necessary prior to entry into the study
- Patient has received stable, standard medical therapy for at least one month with no new medications to treat the disease introduced in the last month.
- Pre-existing condition (e.g. thromboembolic risk, diabetes, hypercholesterolemia) are adequately controlled in the opinion of the investigator
- Fertile patients (male and female) must agree to use an appropriate form of contraception while participating in the study.

Exclusion Criteria:

- Female who is pregnant or nursing, or of child-bearing potential and is not using a reliable birth control method, or who intend to become pregnant during the tenure of this study.
- History of prior radiation exposure for oncological treatment.

- History of Bone Marrow Disorder (especially Non-Hodgkin's Lymphoma (NHL), myelodysplastic syndrome (MDS)
- History of abnormal bleeding or clotting.
- History of Liver Cirrhosis.
- End stage renal disease (Creatinine ≤ 3.0 mg / dl) and/or dialysis
- Active clinical infection being treated by antibiotics before one week enrollment
- Inability or unwillingness to comply with the treatment protocol, follow-up, research tests, or give consent.
- History of life-threatening arrhythmias, except if an automated implantable cardioverter defibrillator (AICD) is implanted
- Life expectancy <6 months due to concomitant illnesses
- Known cancer and undergoing treatment; chemotherapy and/or radiotherapy
- Patients receiving treatment with hematopoietic growth factors (e.g., erythropoietin (EPO), granulocyte colony stimulating factor (G-CSF))
- Patients who can not stop anticoagulation therapy (warfarin) 72hrs prior to infusion
- Patients who can not stop anti-platelet therapy (clopidogrel) 7 days prior infusion
- Prior admission for substance abuse
- Body Mass Index (BMI) of 40 kg/m2 or greater
- Patient receiving experimental medication or participating in another clinical study within 30 days of signing the informed consent
- In the opinion of the investigator or the sponsor, the patient is unsuitable for cellular therapy

Contacts and Locations

Locations

Panama

Stem Cell Institute Recruiting

Panama City, Panama

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

Principal Investigator: Jorge Paz-Rodriguez, MD

Investigators

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

More Information

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