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Umbilical Cord Tissue-derived Mesenchymal Stem Cells for Rheumatoid Arthritis

This study is currently recruiting participants. (see [Contacts and Locations](#))*Verified November 2013 by Translational Biosciences***Sponsor:**

Translational Biosciences

Information provided by (Responsible Party):

Translational Biosciences

ClinicalTrials.gov Identifier:

NCT01985464

First received: October 31, 2013

Last updated: November 8, 2013

Last verified: November 2013

[History of Changes](#)[Full Text View](#)[Tabular View](#)[No Study Results Posted](#)[Disclaimer](#)[? How to Read a Study Record](#)

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.

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

Resource links provided by NLM:[Genetics Home Reference](#) related topics: [rheumatoid arthritis](#)[MedlinePlus](#) related topics: [Rheumatoid Arthritis](#)[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 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 Study Completion Date: June 2016
 Estimated Primary Completion Date: December 2015 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
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 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 \geq 28.0%, White Blood Cell count \leq 14,000, Platelet count \geq 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 \leq 140 and a diastolic blood pressure of \leq 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 \leq 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

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: NCT01985464

Locations**Panama**

Stem Cell Institute

Panama City, Panama

Contact: Aileen Batista +507 306-2600 trials@translationalbiosciences.com

Principal Investigator: Jorge Paz-Rodriguez, MD

Recruiting**Sponsors and Collaborators**

Translational Biosciences

Investigators

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

▶ More Information

No publications provided

Responsible Party: Translational Biosciences
 ClinicalTrials.gov Identifier: [NCT01985464](#) [History of Changes](#)
 Other Study ID Numbers: TBS-UCMSCRA-001
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Keywords provided by Translational Biosciences:

rheumatoid arthritis
umbilical cord
mesenchymal
stem cells

Additional relevant MeSH terms:

Arthritis
Arthritis, Rheumatoid
Joint Diseases
Musculoskeletal Diseases
Rheumatic Diseases
Connective Tissue Diseases

Autoimmune Diseases
Immune System Diseases
Antirheumatic Agents
Therapeutic Uses
Pharmacologic Actions

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