Autologous Adipose Tissue Stromal Vascular Fraction Cells for Rheumatoid Arthritis

This study is currently recruiting participants.

Verified October 2013 by Translational Biosciences

Sponsor:
Translational Biosciences

Information provided by (Responsible Party):
Translational Biosciences

ClinicalTrials.gov Identifier:
NCT01885819

First received: June 18, 2013
Last updated: October 29, 2013
Last verified: October 2013
History of Changes

Purpose

Autologous stromal vascular fraction (SVF) injected at 8 and 10 days after extraction is safe and useful procedure in inducing remission of RA in patients resistant to standard DMARD therapy.

Condition	Intervention	Phase
Rheumatoid Arthritis	Biological: Autologous stromal vascular fraction 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 Non-Expanded Autologous Adipose Tissue Derived Stromal Vascular Fraction Cells 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: 6 months] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Change from baseline 28-DAS Score at 6 months [Time Frame: 6 months] [Designated as safety issue: No]
- Change from baseline EULAR Response Criteria at 6 months [Time Frame: 6 months] [Designated as safety issue: No]
  Change in European League against Rheumatism (EULAR) response criteria and immunological parameters from baseline to 6 months.
- Change from baseline quality of life measure (based on Stanford HAQ) at 6 months [Time Frame: 6 months] [Designated as safety issue: No]
- Change from baseline C-reactive protein at 6 months [Time Frame: 6 months] [Designated as safety issue: No]
- Change from baseline erythrocyte sedimentation rate (ESR) at 6 months [Time Frame: 6 months] [Designated as safety issue: No]
- Change from baseline anti-citrulline antibody measure at 6 months [Time Frame: 6 months] [Designated as safety issue: No]
- Change from baseline rheumatoid factor (RF) at 6 months [Time Frame: 6 months] [Designated as safety issue: No]

Estimated Enrollment:	20
Study Start Date:	June 2013
Estimated Study Completion Date:	December 2015
Estimated Primary Completion Date:	July 2014 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Treatment Autologous stromal vascular fraction cells	Biological: Autologous stromal vascular fraction cells

Detailed Description:

The proposed study will assess primarily safety and secondary efficacy endpoints of autologous stromal vascular fraction (SVF) cells administered to 20 patients with disease modifying antirheumatic drug (DMARD)-resistant Rheumatoid Arthritis (RA) who have been nonresponsive 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 1, 2, 3 and 6 of efficacy endpoints of CRP, ESR, anti-citrulline antibody, 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 and older
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.

Nonresponsive 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 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, ALT, AST 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 NHL, 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., EPO, 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

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Contacts and Locations

Please refer to this study by its ClinicalTrials.gov identifier: NCT01885819

Contacts

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

Locations

Panama

Stem Cell Institute **Recruiting**
Panama City, Panama
Principal Investigator: Jorge Paz-Rodriguez, MD

Sponsors and Collaborators

Translational Biosciences

Investigators

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

More Information

No publications provided

Responsible Party:	Translational Biosciences
ClinicalTrials.gov Identifier:	NCT01885819 History of Changes
Other Study ID Numbers:	TBS-SVF-AR-002-2013
Study First Received:	June 18, 2013
Last Updated:	October 29, 2013
Health Authority:	Panama: Ministry of Health

Keywords provided by Translational Biosciences:
Adipose stromal vascular fraction
Rheumatoid arthritis
adult 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

ClinicalTrials.gov processed this record on October 30, 2013

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