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Safety and Feasibility Study of Autologous Stromal Vascular Fraction (SVF) Cells for Treatment of Osteoarthritis

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

Translational Biosciences

Information provided by (Responsible Party):

Translational Biosciences

ClinicalTrials.gov Identifier:

NCT01885832

First received: June 18, 2013

Last updated: October 29, 2013

Last verified: October 2013

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

Purpose

Autologous stromal vascular fraction (SVF) injected into joints of 20 patients with grade 2, 3, or 4 radiographic OA severity will be safe and feasible as assessed by lack of treatment associated adverse events. Improvements in joint function as assessed by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) are anticipated.

<u>Condition</u>	<u>Intervention</u>	<u>Phase</u>
Osteoarthritis	Biological: Autologous adipose tissue stromal vascular fraction	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: Safety and Feasibility Study of Autologous Stromal Vascular Fraction (SVF) Cells for Treatment of Osteoarthritis

Resource links provided by NLM:[MedlinePlus](#) related topics: [Osteoarthritis](#)[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 Kellgren-Lawrence classification at 6 months [Time Frame: 6 months] [Designated as safety issue: No]
- Change from baseline WOMAC Assessment 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)

<u>Arms</u>	<u>Assigned Interventions</u>
Experimental: Treatment In the treatment arm, autologous stromal vascular fraction (SVF) will be injected into joints of 20 patients with grade 2, 3, or 4 radiographic OA severity.	Biological: Autologous adipose tissue stromal vascular fraction

Detailed Description:

The proposed study is a single center, unblinded, non randomized, phase I/II trial in which the patients will be treated with a single dose of autologous stromal vascular cells (SVF) isolated from 500 ml of adipose tissue extracted from the infraumbilical area. The cellular product will be administered via intra-articular injection into patients with moderate to severe osteoarthritis (OA). Administration will be performed by injection into the synovial space. The dosing regimen will consist of two intraarticular injection of autologous SVF into the index knee. Total injection volume will be about 30 mL in two 15 mL aliquots via a 23 gauge needle inserted 1.5 cm. deep into the intraauricular space of the knee. The total number of SVF to be injected is 1.0×10^7 to 5×10^7 .

The purpose of this study will be to define the safety and efficacy of SVF therapy in improving joint function and the quality of life in patients with OA of the knee. We plan to enroll twenty subjects for treatment for an adequate sample size for safety analysis with signals of efficacy. The primary safety outcome will be tabulation of adverse events related to treatment. Efficacy will be quantified at 3, 6 and 12 months by the total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

▶ Eligibility

Ages Eligible for Study: 18 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria**Inclusion Criteria:**

Age >18 years and ability to understand the planned treatment.

Idiopathic or secondary osteoarthritis of the knee with grade 2, 3, or 4 radiographic severity, as defined by the modified Kellgren-Lawrence classification

Ability and willingness to undergo liposuction

Exclusion Criteria:

Pregnant women or cognitively impaired adults.

Presence of large meniscal tears ("bucket handle" tears), as detected by clinical examination or by magnetic resonance imaging.

Inflammatory or postinfectious arthritis.

More than 5 degrees of varus or valgus deformity.

Kellgren Lawrence grade 4 osteoarthritis in two compartments (the medial or lateral compartments of the tibiofemoral joint or the patellofemoral compartment) in persons over 60 years of age.

Intraarticular corticosteroid injection within the previous 3 months.

A major neurologic deficit.

Serious medical illness with a life expectancy of less than 1 year.

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

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: NCT01885832

Contacts

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

Locations

Panama

Stem Cell Institute **Recruiting**
Panama City, Panama

Sponsors and Collaborators

Translational Biosciences

Investigators

Principal Investigator: Jorge Paz-Rodriguez, M.D. Stem Cell Institute Panama

▶ More Information

No publications provided

Responsible Party: Translational Biosciences
ClinicalTrials.gov Identifier: [NCT01885832](#) [History of Changes](#)
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Study First Received: June 18, 2013
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Health Authority: Panama: Ministry of Health

Keywords provided by Translational Biosciences:

autologous adipose stem cells
stromal vascular fraction
osteoarthritis

Additional relevant MeSH terms:

Osteoarthritis
Arthritis
Joint Diseases
Musculoskeletal Diseases
Rheumatic Diseases

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