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

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:
NCT01885832

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

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.

Condition	Intervention	Phase
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)

Arms	Assigned Interventions

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 x 10(7) to 5 x 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

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

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Other Study ID Numbers: TBS-**SVF**-OA-002-2013

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Last Updated:	October 29, 2013
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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