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

Safety and Feasibility Study of Mesenchymal Trophic Factor (MTF) for Treatment of Osteoarthritis

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:	NCT02003131

Purpose

Allogeneic mesenchymal trophic factors (MTF) from human umbilical cord tissue-derived mesenchymal stem cells (UC-MSC) injected into the knee joints of 20 patients (group 1) or injected subcutaneously into 20 patients (group 2) is a safe and useful procedure for inducing joint function improvements in osteoarthritis (OA) patients with grade 2, 3, or 4 radiographic OA severity.

Condition	Intervention	Phase
Osteoarthritis of the Knee	Biological/Vaccine: Trophic factors from umbilical cord mesenchymal stem cells	Phase 1/ Phase 2

Study Type: Interventional
Study Design: Treatment, Single Group Assignment, Open Label, Non-Randomized, Safety/Efficacy Study
Official Title: Safety and Feasibility Study of Mesenchymal Trophic Factor (MTF) for Treatment of Osteoarthritis

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 joint function from baseline WOMAC assessment at 12 months [Time Frame: 12 months] [Designated as safety issue: No]
- Number of participants with a change in radiogrpahic evidence of knee OA from baseline Kellegren-Lawrence grading system at 12 months [Time Frame: 12 months] [Designated as safety issue: No]

Estimated Enrollment: 40
Study Start Date: December 2013
Estimated Primary Completion Date: December 2015
Estimated Study Completion Date: June 2016

Arms	Assigned Interventions
Intra-articular knee injection of MTF Trophic factors from umbilical cord mesenchymal stem cells administered intra-articularly.	Biological/Vaccine: Trophic factors from umbilical cord mesenchymal stem cells
Subcutaneous injection of MTF Trophic factors from umbilical cord mesenchymal stem cells administered subcutaneously once per week for 12 weeks.	Biological/Vaccine: Trophic factors from umbilical cord mesenchymal stem cells

Detailed Description:

The proposed study will assess primary safety and secondary efficacy endpoints of allogeneic UC-MSC-derived MTF administered to two arms osteoarthritis patients with grade 2, 3, or 4 radiographic OA severity (20 per arm). The first arm will receive an intra-articular injection of MTF into the knee joint under fluoroscopy. The second arm will receive 12 subcutaneous MTF injections, once per week.

For both arms, 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 joint function improvement as assessed by Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).

Eligibility

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

Criteria

Inclusion Criteria:

- Age >18 years and ability to understand the planned treatment.
- Subjects 18 years of age or older with idiopathic or secondary osteoarthritis of the knee with grade 2, 3, or 4 radiographic severity, as defined by the modified Kellgren–Lawrence classification

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 post infectious 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.
- Intra-articular 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

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:	Jorge Paz-Rodriguez, MD	Translational Biosciences / Stem Cell Institute

More Information

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