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

Clinical Study of Umbilical Cord Tissue Mesenchymal Stem Cells (UC-MSC) 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:	NCT02237846

Purpose

Allogeneic human umbilical cord tissue-derived stem cells injected intravenously (IV) once per day for 3 days or once intra-articularly are a safe and will induce a therapeutic effect in osteoarthritis (OA) patients.

Condition	Intervention	Phase
Osteoarthritis of the Knee	Biological/Vaccine: Human umbilical cord tissue-derived mesenchymal stem cells	Phase 1/ Phase 2

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study
Official Title: Clinical Study of Umbilical Cord Tissue Mesenchymal Stem Cells (UC-MSC) for Treatment of Osteoarthritis

Further study details as provided by Translational Biosciences:

Primary Outcome Measure:

- Number of participants with adverse events [Time Frame: 3 months and 12 months] [Designated as safety issue: Yes]

Secondary Outcome Measures:

- Number of participants with a change in joint function from baseline WOMAC assessment [Time Frame: 3 months and 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 [Time Frame: 3 months and 12 months] [Designated as safety issue: No]

Estimated Enrollment: 40
Study Start Date: September 2014
Estimated Primary Completion Date: September 2016
Estimated Study Completion Date: March 2017

Arms	Assigned Interventions
Active Comparator: Intra-articular knee injection of UC-MSC Human umbilical cord tissue-derived mesenchymal stem cells administered into the knee joint once	Biological/Vaccine: Human umbilical cord tissue-derived mesenchymal stem cells
Active Comparator: IV injection of UC-MSC Human umbilical cord tissue-derived mesenchymal stem cells administered once per day for 3 consecutive days	Biological/Vaccine: Human umbilical cord tissue-derived mesenchymal stem cells

Detailed Description:

The proposed study will assess primarily safety and secondary efficacy endpoints of allogeneic umbilical cord mesenchymal stem cells (UC-MSC) administered to 40 patients with OA. Arm 1 will receive one intra-articular injection of UC-MSC into the knee and Arm 2 will receive IV UC-MSC once per day for 3 consecutive days.

The primary objective of the trial is freedom from treatment associated adverse events at 3 and 12 months post treatment. Secondary objective will be efficacy as assessed at baseline, and 3 and 12 months post treatment and will be quantified based on the Western Ontario and McMaster 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:

- Signed informed consent by the subject.
- Age greater than or equal to 18 years
- 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
- Must have proof of health insurance coverage for treatment-related fees from a verifiable source or financial means to pay up to $11,500 for treatment-related fees and ancillary study-related expenses.

Exclusion Criteria:

- Pregnant or lactating women
- Women of childbearing potential unwilling to use two forms of contraception
- 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

Contacts and Locations

Locations

Panama

Stem Cell Institute Recruiting

Panama City, Panama

Contact: Laysa Adames (817) 945-9228 trials@translationalbiosciences.com

Investigators

Principal Investigator: Ruben Berrocal, MD Unaffiliated

More Information

Responsible Party:	Translational Biosciences
Study ID Numbers:	CNEI-2014-TBS-UCMSCOA-001
Health Authority:	Panama: Ministry of Health