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## Clinical Study of Umbilical Cord Tissue Mesenchymal Stem Cells (UC-MSC) for Treatment of Osteoarthritis

**This study is currently recruiting participants. (see [Contacts and Locations](#))**

Verified September 2014 by Translational Biosciences

### Sponsor:

**Translational Biosciences**

### Information provided by (Responsible Party):

Translational Biosciences

### ClinicalTrials.gov Identifier:

NCT02237846

First received: September 9, 2014

Last updated: NA

Last verified: September 2014

History: No changes posted

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### ► 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.

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

Study Type: Interventional

Study Design: Allocation: Randomized

Endpoint Classification: Safety/Efficacy Study

Intervention Model: Parallel Assignment

Masking: Open Label

Primary Purpose: Treatment

Official Title: Clinical Study of Umbilical Cord Tissue Mesenchymal Stem Cells (UC-MSC) 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: 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 radiographic evidence of knee OA from baseline Kellgren-Lawrence grading system [ Time Frame: 3 months and 12 months ] [ Designated as safety issue: No ]

Estimated Enrollment: 40  
 Study Start Date: September 2014  
 Estimated Study Completion Date: March 2017  
 Estimated Primary Completion Date: September 2016 (Final data collection date for primary outcome measure)

<u>Arms</u>	<u>Assigned Interventions</u>
Active Comparator: Intra-articular knee injection of UC-MSC Human umbilical cord tissue-derived mesenchymal stem cells administered into the knee joint once	Biological: 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: 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/m<sup>2</sup> 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**

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: NCT02237846

### **Locations**

#### **Panama**

Stem Cell Institute

Panama City, Panama

Contact: Margie Arosemena +507 306-2612 (Panama) [trials@translationalbiosciences.com](mailto:trials@translationalbiosciences.com)

#### **Recruiting**

### **Sponsors and Collaborators**

#### **Translational Biosciences**

#### **Investigators**

Principal Investigator: Ruben Berrocal, MD

## ▶ **More Information**

No publications provided

Responsible Party: Translational Biosciences  
ClinicalTrials.gov Identifier: [NCT02237846](#) [History of Changes](#)  
Other Study ID Numbers: CNEI-2014-TBS-UCMSCOA-001  
Study First Received: September 9, 2014  
Last Updated: September 9, 2014  
Health Authority: Panama: Ministry of Health

Keywords provided by Translational Biosciences:

osteoarthritis  
knee  
stem cells  
mesenchymal  
umbilical cord

Additional relevant MeSH terms:

Osteoarthritis	Joint Diseases
Osteoarthritis, Knee	Musculoskeletal Diseases
Arthritis	Rheumatic Diseases

ClinicalTrials.gov processed this record on September 18, 2014

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