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

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

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: 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/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

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 — **Recruiting**
Panama City, Panama
Contact: Marggie Arosemena +507 306-2612 (Panama) trials@translationalbiosciences.com

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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