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STEM CELL CLINICAL TRIAL: Treatment of Knee Osteoarthritis With Autologous Mesenchymal Stem Cells

Sponsor: Red de Terapia Celular

Collaborator: Fundacion Teknon, Centro Medico Teknon, Barcelona University of Valladolid Centro en Red de Medicina Regenerativa de Castilla y Leon Institut de Terapia Regenerativa Tissular EGARSAT Suma Intermutual, Barcelona, Spain Cetir Sant Jordi, S.a.

BACKGROUND:

- Osteoarthritis is the most prevalent joint disease and frequently leads to joint pain, functional loss, and disability with conventional treatments only producing minimal benefits. The objective of this study was to assess the feasibility and safety of using autologous Mesenchymal Stem Cells (MSCs) as a cellular based therapy for osteoarthritis.
- Standard treatment for osteoarthritis includes physical and educational therapy, symptomatic treatment with acetaminophen or nonsteroidal anti-inflammatory drugs, and sometimes local corticosteroid injection.
- However these therapies have often demonstrated little to no clinical benefit.
- The use of autologous cellular based therapies has been applied in regenerative medicine for more than 20 years with MSCs being a current potential candidate for such treatments

METHOD:

- The study included 12 participants, 6 male and 6 female with an average age of 49 years old.
- All participants were diagnosed with osteoarthritis of the knee by two independent observers.
- Previous to the trial, all participants were unresponsive to conservative treatments, with 9 out of 12 having undergone a corrective surgery.
- Autologous MSCs were collected from bone marrow harvested from the iliac crest and expanded in culture to 40 million cells in approximately 22 days under Good Manufacturing Practices (GMP).
- Medial parapatellar injections were performed using a cell suspension of 5 million cells/mL.
- No adverse events occurred with only mild local pain and discomfort being reported in half of the participants.

RESULTS:

- The clinical trial resulted in a significant reduction of pain for all participants as early as 3 months following injection, with all those involved also reporting satisfaction with the treatment and lasting pain relief through the one year observation period.
- Magnetic Resonance Imaging (MRI) was also used to assess cartilage quality.
- Results indicated a reduction in poor cartilage areas in 11 of the 12 participants.
- A two year follow up MRI was also performed indicating that quality of cartilage further improved over time in addition to pain improvements being maintained.

CONCLUSION:

• Overall the data compiled by this study and it's 2 year follow up, indicate autologous MSC treatment as a safe and feasible therapy for osteoarthritis resulting in effective and durable pain relief in addition to cartilage improvement.

ASSOCIATED PUBLICATIONS:

- https://clinicaltrials.gov/ct2/bye/rQoPWwoRrXS9-i-wudNgpQDxudhWudNzlXNiZip9Ei7ym67VZR 0RcK4txRFtA6h9Ei4L3BUgWwNG0it.
- https://clinicaltrials.gov/ct2/bye/rQoPWwoRrXS9-i-wudNgpQDxudhWudNzlXNiZip9Ei7ym67VZR 0VOK4w-gCnA6h9Ei4L3BUgWwNG0it.