Proposed Clinical Trial to Evaluate the efficacy of Umbilical Cord Blood derived Mesenchymal Stem Cells in treatment of Osteoarthritis of the Knee

Description:

Randomized single blinded Placebo controlled Multicenter multinational clinical trial

Invitrx umbilical cord blood stem cells

Background:

Osteoarthritis is a serious medical condition for which adequate conservative treatment is lacking. Recent Research and Academic groups have called for evaluating characterized and uncharacterized cellular therapy. Similar to other areas of medicine, evidence for the effectiveness of orthopedic services is not always identifiable. An important distinction to make is that even though available data is lacking or evidence is absent, a recommendation is not assumed to be ineffective

Evidence based on pilot studies with consistent findings for recommending for intervention with stem cells is mounting. A strong recommendation reveals that the benefits of the recommended approach clearly exceed the potential harm and that the quality of the supporting evidence is high.

The purpose of this study is to determine the appropriateness of clinical stem cell therapy for the heterogeneous OA patient population routinely seen in practice. The best available scientific evidence is synthesized and developed into this clinical protocol for appropriate management of symptoms of knee osteoarthritis. We propose that when there is evidence corroborated by consensus that expected benefits substantially outweigh potential risks exclusive of cost, a procedure is determined to be appropriate.

Aligned with the American Academy of Orthopedic Surgeons (AAOS), the authors' philosophy is that evidence-based medicine is an integral component of treatment decisions and that the best results are predicated on reciprocal communication between the patient and physician and an individualized regimen where risks are minimized and benefits are maximized. Medical expertise that is informed by research and takes into account that the possible options increases the likelihood that patients' symptoms will be managed effectively.

METHODS:

Ten treatment locations in four different countries will be selected study locations. Each location will select ten patients with known knee OA. Strict medical records shall be documented in keeping with best clinical practice. Medication allergies will be assessed and documented. Every patient will receive medical counseling and stem cell education. Every patient must provide informed consent in written format.

Each patient selected shall meet the following criteria:

1) Orthopedic surgeon diagnosis of Knee OA;
2) Pain of 8/10 + on the Visual Analog Scale (VAS)
3) Radiographic evidence of OA - Xray
4) Failed Physical Therapy

All patients will have pretreatment blood work inclusive of CBC, Chem 7; ESR, CRP, Lipid profile, Hgb A1c and serum testosterone levels

Post treatment blood work will be done with the same profile at 2 months, 4 months, 6 months and 8 months

Pretreatment MRI; Repeat MRI at 4 months

Each patient will be randomized into treatment group vs placebo group

Treatment is an in-office injection and follow the injection protocol:

Injection description: The right/left knee was prepped and draped using standard sterile techniques. The anterior medial approach was used and the skin and subcutaneous region was injected with a mixture of 3 cc of 1% lidocaine & 2 cc of 0.5 % Marcaine and a skin anesthesia was obtained. Thereafter, the UCBSC was obtained from the -80°C tissue bank freezer and rapidly brought to room temperature. The stem cells were handled with sterile techniques and expanded with 3cc of Normal Saline. The syringe with the Stem Cell solution was introduced into the medial compartment with a 22 gauge 1 1/2 inch needle. The solution was slowly injected over a one-minute interval intra-articularly with interval pause to assess for any adverse reaction. No adverse reaction was noted. The spinal needle was then atraumatically removed and a compressive bandage was then placed over the injection site.

Placebo: 5cc normal saline. Same protocol as above

OUTCOMES ASSESSMENT TOOLS:

the critical outcomes to be assessed:

• Pain

• Functional status

• Disability

• Other arthritis-related symptoms

Measurement tools:

1) Visual Analog Scale (VAS) 0-10
2) AAOS knee society score
3) Oxford knee score

4) Patient Blood test
5) Radiographic Studies – Xrays; MRI – comparison of pretreatment MRI to same format MRI at 4 months

Study Cautions and Considerations

• Adequate statistical power

• Stochastic random assignment of patients to comparison groups

• Sufficient blinding to mitigate against a placebo effect

• Comparability of the patient groups at the beginning of the study

• Delivery of treatment in a manner where observed differences between the comparison groups could reasonably be attributed to the treatment

• Validated outcome measures

• Absence of investigator bias