Dose Escalation Pilot Study to Evaluate the Safety of Alocyte for the Treatment of Facetogenic Back Pain

ClinicalTrials.gov ID NCT05909709 **(IND approved by FDA April 20th, 2022)**

Study Details | Dose Escalation Pilot Study to Evaluate the Safety of Alocyte for the Treatment of Facetogenic Back Pain | ClinicalTrials.gov

Brief Summary

The purpose of this study is to see if the use of Alocyte (cord blood plasma plus mononucleic cells) will be safe, well tolerated, and whether it causes any side effects. The study will also examine if the use of the Investigational Product (IP) is able to reduce local inflammation or alleviate Facetogenic back pain

Detailed Description

Ghormley, in 1933, was the first to perform oblique spine radiographs to view the zygapophysial or facet joints and coin the term "facet syndrome" to refer to LBP with "sciatica" originating from the facet joints. The facet joint may be affected by systemic disease, such as rheumatoid arthritis and ankylosing spondylitis, or be site of micro traumatic fractures, such as osteoarthritis, meniscoid entrapment, synovial impingement, joint subluxation, synovial inflammation, loss of cartilage, and mechanical injury. Facetogenic pain is the result of repetitive stress and/or cumulative low-level trauma, leading to inflammation and stretching of the joint capsule.

Current treatment options for this disease are limited to symptomatic treatment, including analgesics, physiotherapy, and minimally invasive or surgical treatment (spinal fusion or non-fusion), but none of the methods addresses the underlying problem. The pathological process of intervertebral disc degeneration cannot be prevented by these therapies.

Alocyte is a cellular, minimally manipulated product derived from umbilical cord blood. Alocyte's manufacturing methodology is designed to enrich human umbilical cord plasma and human umbilical cord blood-derived mononuclear cells (hematopoietic lineage cells such as lymphocytes, monocytes, stem and progenitor cells, as well as mesenchymal stem cells) present in full-term cord blood. The final product is composed of a heterogenous population of cellular products, mainly the exosomes, cytokines, and nucleated cells.

Cytokine expression of Alocyte was fully evaluated. Alocyte showed a robust expression of RANTES, Osteopontin, and Angiostatin where the first two are stem cell repair cytokines and the latter is pro-angiogenic cytokine. Other cytokine showed moderate levels are IL-8, PDGF-BB, TIMP-1, TIMP-2, Angiopoietin-1, Angiogenin, MMP-9, Tie-2, uPAR, BDNF, TGF-ß2, GRO, IGFBP-1, IGFBP-2, IL-8, IL-12-p40, MIF, and NAP-2. Alocyte contained a variety of pro-angiogenic, immune-modulatory, anti-inflammatory, pro-metabolism, and tissue repair growth factors.

Therefore, a regenerative approach for treating Facetogenic pain will be beneficial by promoting changes in the pathogenic mechanism triggered by the cellular therapeutic product Alocyte.