Denver back pain specialists start enrollment in stem cell therapy study in chronic back pain subjects

NEWS

Pain Management

Denver Back Pain Specialists announced, its first patient enrolled in a nationwide FDA- cleared adult stem cell study (phase 3) testing an investigational treatment for chronic low back pain associated with degenerative disc disease. This study evaluates the use of Mesenchymal Precursor Cells (MPCs) – adult stem cells derived from bone marrow and injected into the lumbar disc.

An estimated 30 million people in the U.S. experience back pain. Low back pain is mainly caused by degenerative disc disease, which develops with the gradual loss of proteoglycan that cushions the bones of the spine and enables normal motion.

Low back pain patient respond to physical therapy and medications, but in advanced cases, artificial disc replacement or spinal fusion may be performed but these surgeries are not entirely effective. Minimally invasive stem cell procedure may offer improvement to chronic pain from degenerative disc disease.

J. Scott Bainbridge M.D., Denver Back Pain Specialists' principal investigator of this study sees the critical need for a minimally invasive solution to a common, debilitating condition. He said "The clinical program is the first of its kind in the United States and we are very excited by the potential of these adult stem cells to provide a novel therapeutic approach".

In Phase 3 study, approximately 330 study participants enrolled. Up to 20 participants enrolled at the Denver site and the rest at other medical centers throughout the U.S. Patients will be followed for 12 months post-treatment.

The study participants included those suffering from moderate to severe low-back pain for a minimum of six months and who did not respond to conventional treatments. Patients are randomly assigned into three treatment groups:

1. One third will receive a 6 million cell dose of MPCs + hyaluronic acid, a substance that facilitates localization and retention of the stem cells;

2. One third will receive a 6 million cell dose of MPCs alone;

3. One third will receive saline solution.

In an outpatient procedure, patients will receive a single injection of test agent, MPCs, directly into the center of the target spinal disc and will be monitored for safety and efficacy. Patients will monitor using imaging to identify any changes in their disease condition or progression. Use of pain medications, self-reports of pain, subsequent surgical interventions and assessments of disability, quality of life, repair of the discs, function, reduction of pain and activity will be evaluated in each patient.

Dr. Bainbridge took part in the preceding phase 2 clinical trial, found that 6 million cell doses resulted in a greater proportion of patients achieving reduced back pain as compared to patients who did not receive the cells and cells were also well tolerated.

This study is sponsored by Mesoblast Limited, a world leader in cell-based regenerative medicine. Mesoblast has the worldwide exclusive rights to a series of patents and technologies developed over more than 10 years relating to the identification, extraction, culture and uses of MPCs.

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