Randomized Controlled Trial

The Safety and Effectiveness of Orthobiologic Injections for Discogenic Chronic Low Back Pain: A Multicenter Prospective, Crossover, Randomized Controlled Trial with 12 Months Follow-up

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Background: Chronic low back pain is one of the most common causes of disability, affecting more than 600 million people worldwide with major social and economic costs. Current treatment options include conservative, surgical, and minimally invasive interventional treatment approaches. Novel therapeutic treatment options continue to develop, targeting the biological cascades involved in the degenerative processes to prevent invasive spinal surgical procedures. Both intradiscal platelet-rich plasma (PRP) and bone marrow concentrate (BMC) applications have been introduced as promising regenerative treatment procedures.

Objectives: The primary objective of this study is to assess the safety and effectiveness of an orthobiologic intradiscal injection, PRP or BMC, when compared to control patients. The secondary objectives are to measure: patient satisfaction and incidence of hospitalization, emergency room visit and spine surgery at predetermined follow-up intervals.

Study Design: A multicenter, prospective, crossover, randomized, controlled trial.

Setting: Comprehensive Spine and Sports Center and participating centers.

Methods: Forty patients were randomized into saline trigger point injection, intradiscal PRP, or BMC. Follow-up was 1, 3, 6, and 12 months posttreatment. Placebo patients were randomized to PRP and BMC injection if < 50% decrease in numeric rating scale (NRS) scores in 3 months, while PRP and BMC patients to the other active group if < 50% decrease in NRS scores in 6 months.

Results: Both PRP and BMC demonstrated statistically significant improvement in pain and function. All the placebo patients reported < 50% pain relief and crossed to the active arm. None of the patients had any adverse effects, hospitalization, or surgery up to 12 months posttreatment.

Limitations: The limitations of our study were the small number of patients and open-label nature of the study.

Conclusion: This is the only human lumbar disc study that evaluates both PRP and BMC in the same study and compares it to placebo. PRP and BMC were found to be superior to placebo in improving pain and function; however, larger randomized clinical trials are needed to answer further questions on the comparative effectiveness of various biologics as well as to identify outcome differences specific to disc pathology.

Key words: Low back pain, disc, mesenchymal stem cells, platelet-rich plasma, biologics, back pain, degenerative disc disease, intradiscal biologics, lumbar spine, low back, regenerative treatment spine, radiculopathy

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