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Plasma Rich in Growth Factors (PRGF-Endoret) in the Treatment of Symptomatic Knee Osteoarthritis: A Randomized Clinical Trial

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Summary:

This multicenter, double-blind, hyaluronic acid-controlled clinical trial evaluated the efficacy and safety of PRGF-Endoret, an autologous biological therapy for regenerative purposes, as a treatment for knee pain from osteoarthritis.

Abstract:

Background:

This multicenter, double-blind, hyaluronic acid-controlled clinical trial evaluated the efficacy and safety of PRGF-Endoret, an autologous biological therapy for regenerative purposes, as a treatment for knee pain from osteoarthritis.

Methods:

We randomly assigned 176 patients with symptomatic knee osteoarthritis to receive infiltrations with PRGF-Endoret or with hyaluronic acid (three injections on a weekly basis). The primary outcome measure was a 50 percent decrease in knee pain from baseline to week 24. We also assessed pain, stiffness, and physical function using the WOMAC Index; the rate of response using the criteria of the OMERACT-OARSI; and safety.

Results:

The mean age of the patients was 59.8 years, and 52 percent were women. As compared with the rate of response to hyaluronic acid, the rate of response to PRGF-Endoret was 14.1 percentage points higher (P=0.044). Regarding the secondary outcome measures, the rate of response to PRGF-Endoret was in all the cases higher, although no significant differences were reached. For patients with moderate to severe pain at baseline, the rate of response to PRGF-Endoret was 26 percentage points higher (P=0.086) than the rate of response to hyaluronic acid, although no significant differences were reached. Adverse events were mild and evenly distributed among the groups.

Conclusions:

PRGF-Endoret has both a faster time to response and more enduring beneficial effect than hyaluronic acid. Treatment with PRGF-Endoret resulted in clinically significant reductions in knee pain, stiffness and physical function, with mild adverse effects, in patients with knee osteoarthritis. (Funded by BTI Biotechnology Institute; ClinicalTrials.gov number, NCT00782197).