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

Mikel Sanchez Alvarez, MD, SPAIN
Eduardo Anitua, MD, PhD, SPAIN
Jorge Guadilla, MD, SPAIN
Juan Azofra, MD, SPAIN
Nicolas Fiz, MD, SPAIN
Beatriz Aizpurua, MD, SPAIN
Tomokazu Yoshioka, MD, SPAIN
Jaime Usabiaga, MD, SPAIN
Javier Albillos, MD, SPAIN
R. Garate, MD, SPAIN
Jose Javier Aguirre, MD, PhD, SPAIN
Gorka Orive, PhD, SPAIN
USP Clinica La Esperanza
Vitoria-Gasteiz, Alava, SPAIN

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 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).