LONG-TERM EFFICACY AND SAFETY OF A COMBINED HYALURONIC ACID IN OSTEOARTHRITIS OF THE KNEE

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Abstract

Objective: To evaluate the long-term efficacy and safety of a combined HA of low and high molecular weight and different compositions (DHM) in comparison with low molecular weight HA (LMW, 500–700 kDa) in high molecular weight HA (HMW, 6 million Da), in a randomized, placebo-controlled, 104-week, single-center, double-blind, parallel-group study in patients with grade 2–4 osteoarthritis (OA) of the knee.

Design: A randomized, double-blind, placebo-controlled, 1:1:1 parallel-group study in patients with knee OA enrolled at 27 centers in 14 countries (100 patients per group). Randomized equally to DHM, LMW, or HMW groups.

Patients: A total of 300 patients (mean age 58 years, 75% female) in the DHM group, 300 patients (mean age 58 years, 75% female) in the LMW group, and 299 patients (mean age 57 years, 75% female) in the HMW group were enrolled. Patients had moderate-to-severe knee OA (Kellgren and Lawrence grade ≥2) with a baseline VAS pain score ≥40 mm.

Intervention: Patients were treated with a single intra-articular injection of DHM (2 mL, 7.5 mg HA; 500–700 kDa, 6 million Da), LMW (2 mL, 7.5 mg HA, 500–700 kDa), or HMW (2 mL, 7.5 mg HA, 6 million Da) at baseline and week 16, with follow-up assessments at weeks 24, 52, and 104.

Measurements: VAS pain, WOMAC pain subscore, and patient satisfaction were assessed at baseline, week 16, and follow-up visits. Global patient satisfaction and safety assessments were performed throughout the study.

Outcomes: The primary outcome was the VAS pain score at baseline and at week 16. Secondary outcomes included WOMAC pain subscore, global patient satisfaction, and safety assessments.

Results: At baseline, mean VAS pain was 71.9 mm in the DHM group, 74.0 mm in the LMW group, and 73.1 mm in the HMW group. At week 16, mean VAS pain was significantly lower in the DHM group compared to the LMW and HMW groups (p < 0.001 for both). The global patient satisfaction was significantly higher in the DHM group compared to the LMW and HMW groups (p < 0.001 for both). The incidence of adverse events was lower in the DHM group compared to the LMW and HMW groups (p < 0.001 for both).

Conclusions: The DHM group had superior efficacy and safety compared to the LMW and HMW groups in patients with knee OA. This study demonstrates the potential of a combined HA of low and high molecular weight and different compositions in the management of knee OA.

References:


ANOVA

Statistical analysis was performed using Analysis of Variance (ANOVA) and Fisher’s Least Significant Difference (LSD) test. The significance level was set at p < 0.05.

ANOVA

The data were analyzed using ANOVA followed by Fisher’s LSD test. A p-value of <0.05 was considered statistically significant.

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The differences in VAS pain scores between groups were compared using ANOVA followed by Fisher’s LSD test. A p-value of <0.05 was considered statistically significant.

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