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

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Abstract

OBJECTIVES

The purpose of this double-blind, placebo-controlled study was to assess the safety and efficacy of a combined hyaluronic acid (HAs) in comparison with placebo (PL) or hyaluronic acid of lower molecular weight (LMW) in patients with osteoarthritis of the knee.

METHODS

A total of 244 patients were randomized in a 1:1:1 ratio to receive a combined hyaluronic acid (DMW), consisting of hylan G-FP (HMW), hylan G-FP with low molecular weight polyglucosan (LMW/HMW=10:1), or placebo (PL) once weekly for 12 weeks. The primary endpoint was the change in self-reported walking pain at 12 weeks compared to baseline. A secondary endpoint was the change in self-reported walking pain at 24 weeks compared to baseline. The efficacy analysis included all patients who received at least one dose of study medication and had at least one post-baseline assessment; the safety analysis included all patients who received at least one dose of study medication. All data were analyzed on an intention-to-treat basis.

RESULTS

At 12 weeks, the change in walking pain from baseline was significantly lower in the DMW group compared to the LMW group (P<0.001) and the PL group (P<0.001). At 24 weeks, the change in walking pain from baseline was significantly lower in the DMW group compared to the LMW group (P<0.001) and the PL group (P<0.001). The safety analysis showed no significant differences between the treatment groups in terms of adverse events or changes in laboratory parameters.

CONCLUSION

The combined hyaluronic acid product was well tolerated and significantly improved walking pain in patients with osteoarthritis of the knee compared to placebo and hyaluronic acid of lower molecular weight.

Introduction

Several HA products are currently marketed worldwide for the treatment of knee osteoarthritis. However, the evidence for their efficacy and safety is limited. The purpose of this study was to assess the safety and efficacy of a combined hyaluronic acid product in patients with knee osteoarthritis.

While a single HA product has been shown to be effective in relieving pain and improving function in patients with knee osteoarthritis, there is limited evidence for the long-term efficacy of this therapy. The objective of this study was to determine the long-term efficacy and safety of a combined hyaluronic acid product in patients with knee osteoarthritis.

Subjects with knee osteoarthritis were randomized to receive either a combined hyaluronic acid product (DMW), consisting of hylan G-FP (HMW), hylan G-FP with low molecular weight polyglucosan (LMW/HMW=10:1), or placebo (PL) once weekly for 12 weeks. The primary endpoint was the change in self-reported walking pain at 12 weeks compared to baseline. A secondary endpoint was the change in self-reported walking pain at 24 weeks compared to baseline. The efficacy analysis included all patients who received at least one dose of study medication and had at least one post-baseline assessment; the safety analysis included all patients who received at least one dose of study medication. All data were analyzed on an intention-to-treat basis.

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References