INTRODUCTION

EXPAREL, an investigational long-acting local anesthetic, provided extended pain relief and decreased opioid use after bunionectomy compared to placebo, and therefore may offer clinically meaningful advantages in providing postoperative pain relief.

METHODS

Study Design

A phase 3, multicenter, parallel-group, placebo-controlled, randomized, double-blind study to evaluate the efficacy and safety of the intraoperative administration of EXPAREL compared with placebo.

Postoperative opioid rescue medication consisted of 1–2 tablets of 5 mg oxycodone/325 mg acetaminophen q 4–6 hours as needed to a maximum of 12 tablets per day.

RESULTS

The difference between treatment groups was statistically significant at 2, 4, 6, and 48 hours.

CONCLUSIONS

The study met its primary endpoint with a statistically significant reduction in AUC through 24 hours in the patients receiving EXPAREL compared to placebo (p<0.0005).

No patients demonstrated any evidence of malunion or non-union.

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