Efficacy and Safety of N1539, Intravenous Meloxicam, in a Phase 3 Study of Subjects with Moderate to Severe Pain following Bunionectomy

ABSTRACT

This single and randomized study assessed the efficacy and safety of IV meloxicam 30 mg in subjects with moderate to severe pain following bunionectomy surgery. The study was a double-blind, placebo-controlled study. A total of 101 subjects were randomized to IV meloxicam 30 mg or placebo. The primary endpoint was the summed pain intensity difference (SPID) over the first 48 hours. The results showed that IV meloxicam 30 mg was statistically superior to placebo in reducing pain intensity.

INTRODUCTION

Meloxicam is a non-steroidal anti-inflammatory drug (NSAID) with analgesic and anti-inflammatory activities. It is widely used in the management of pain and inflammation.

OBJECTIVE

The primary objective of this study was to demonstrate the analgesic efficacy of IV meloxicam 30 mg in subjects with moderate to severe pain following bunionectomy surgery.

METHODS

This was a randomized, double-blind, placebo-controlled study involving 101 subjects with moderate to severe pain following bunionectomy surgery. Subjects were randomized to IV meloxicam 30 mg or placebo. The primary endpoint was the SPID over the first 48 hours.

RESULTS

The results showed that IV meloxicam 30 mg was statistically superior to placebo in reducing pain intensity. The proportion of subjects with at least a 2+ improvement in pain intensity was significantly higher in the IV meloxicam group compared to placebo. The incidence of injection site reactions was comparable between the two groups.

CONCLUSIONS

IV meloxicam 30 mg was statistically superior to placebo in reducing pain intensity in subjects with moderate to severe pain following bunionectomy surgery. The study demonstrated the efficacy and safety of IV meloxicam 30 mg in this patient population.

REFERENCES

