HTX-011, a Locally Administered Analgesic, Reduces Postoperative Pain Intensity and Opioid Use Through 72 Hours Across Bony and Soft Tissue Surgical Models

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INTRODUCTION

• Surgery causes pain that is most severe within the first 72 hours.
• Inadequate pain management during this period can lead to adverse outcomes for patients and increased costs for the health care system.

• Systemic opioids are commonly prescribed to manage postoperative pain, but overuse of these drugs heightens the risk for opioid-related adverse events for patients, increases costs for hospitals, and contributes to the wider societal risk for opioid addiction.

• A local anesthetic such as bupivacaine is commonly used for postoperative pain relief but current formulations, including extended-release formulations, deliver limited local analgesic effect beyond 24 hours after surgery.

• HTX-011 (sustained-release bupivacaine + reboxetine) leverages reboxetine in a unique combination with bupivacaine to promote a powerful local analgesic effect, delivered over 72 hours, with the use of Blaschko's law.

• HTX-011 has the potential to significantly advance the treatment of postoperative pain and reduce the need for opioid analgesics across bony and soft tissue surgical models with the first 72 hours after surgery.

OBJECTIVE

• To assess the safety and efficacy of HTX-011 in reducing pain intensity and opioid rescue medication use in subjects undergoing bunionectomy and herniorrhaphy.

METHODS

• This study included 2 randomized, double-blind, placebo-controlled parallel 2 trial clinical trial involving subjects undergoing herniorrhaphy (NCT02272905) or bunionectomy (NCT02636086).

• In this subset, subjects were randomly assigned to receive one of the treatments described in Table 1.

RESULTS

Efficacy

• Subjects treated with HTX-011 experienced significantly less pain (as measured by AUC of pain intensity scores adjusted for opioid use) than did subjects who received bupivacaine or saline placebo through 72 hours after bunionectomy or herniorrhaphy (Figure 1).

• A greater proportion of herniorrhaphy and bunionectomy subjects were opioid free through 72 hours with HTX-011 treatment than with bupivacaine or saline placebo (Figure 2).

• HTX-011 significantly reduced the amount of opioid rescue medication used after bunionectomy and herniorrhaphy (Table 2).

Safety

• The incidence of adverse events in subjects treated with HTX-011, bupivacaine, and saline placebo are presented in Table 4.

CONCLUSIONS

• HTX-011’s unique formulation was well tolerated after bunionectomy and herniorrhaphy and significantly reduced pain intensity through 72 hours.

• HTX-011 significantly reduced the amount of opioid rescue medication used after bunionectomy and herniorrhaphy compared with bupivacaine or saline placebo.

• These results confirm the efficacy of HTX-011 across both bony and soft tissue surgical models.

• HTX-011 may represent an important advance in the prevention and treatment of postoperative pain.

REFERENCES

7. Saunders; 2015.

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