Clinical Trial Report: Evaluation of DPX-200 for Diabetic Peripheral Neuropathy Treatment

Introduction:
This clinical trial evaluates the safety and efficacy of DPX-200, a novel oral medication, in treating diabetic peripheral neuropathy (DPN). DPN is a chronic condition affecting peripheral nerves, causing pain, numbness, and impaired sensory function. It significantly impacts the lives of people with diabetes. DPX-200 is a well-tolerated, selective sodium channel blocker that has demonstrated potential in pre-clinical studies for alleviating neuropathic pain. This double-blind, placebo-controlled trial aims to assess the therapeutic benefits of DPX-200 in improving symptoms associated with DPN.

Methods:
Study Design:
A total of 150 participants with type 2 diabetes mellitus and symptomatic DPN were randomized in a 2:1 ratio to receive DPX-200 (n=100) or a placebo (n=50) once daily for a period of 24 weeks. The study was double-blinded, with an identical-appearing placebo medication administered to the control group.

Inclusion Criteria:
• Age 18 years or older
• Diagnosis of type 2 diabetes mellitus
• Presence of painful DPN with a Visual Analog Scale (VAS) Pain score of 4 or higher
• Numbness or reduced sensation in the feet or lower extremities

Exclusion Criteria:
• Severe cardiovascular disease or renal impairment
• Uncontrolled hypertension
• History of seizures or epilepsy
• Current use of beta-blockers or certain antidepressants
• Pregnancy or breastfeeding

Outcome Measures:
The primary outcome measure was the change in neuropathic pain intensity, assessed using the VAS Pain scale, between the DPX-200 and placebo groups. Secondary outcome measures included:

Sensory function assessment using Semmes-Weinstein Monofilament Testing (SWMT)

Neuropathy Impairment Score (NIS)

Patient and Physician Global Impression of Change (PGIC/PGI-C) scales

Health-related quality of life (HRQoL) evaluation using the EuroQol five-dimensional questionnaire (EQ-5D)

Adverse event monitoring and clinical laboratory tests for safety assessments

Results:
Primary Outcome:
DPX-200 demonstrated significant efficacy in reducing neuropathic pain compared to the placebo group. The mean VAS Pain score decreased by 2.8 points in the DPX-200 group versus 0.9 points in the placebo group ($p<0.001$).

Secondary Outcomes:
• SWMT results showed significant improvements in sensory function in the DPX-200 group, with a higher number of participants achieving a positive response compared to the placebo group ($p<0.05$).
• The NIS demonstrated a mean improvement of -6.1 ± 2.4 points in the DPX-200 group, which was statistically significant compared to the placebo group's improvement of -2.2 ± 1.8 points ($p<0.01$).
• PGIC and PGI-C scales revealed that a higher proportion of patients and physicians reported significant improvements in symptoms in the DPX-200 group ($p<0.05$).
• EQ-5D analysis indicated significant enhancements in HRQoL in the DPX-200 group, particularly in pain and discomfort domains ($p<0.01$).

Safety:

DPX-200 was generally well-tolerated, with no serious drug-related adverse events reported. The most common mild adverse events were dizziness and nausea, which were transient and resolved without discontinuation in most cases. Laboratory tests did not reveal any safety concerns.

Conclusion:
DPX-200 administration resulted in significant improvements in neuropathic pain, sensory function, and overall symptoms associated with DPN. The drug demonstrated a favorable safety profile. These findings suggest that DPX-200 could be a promising and well-tolerated therapeutic option for the management of DPN.

However, further studies with larger sample sizes and longer durations are warranted to confirm the long-term efficacy and safety of DPX-200 in the treatment of DPN.

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