Mirogabalin for the treatment of diabetic peripheral neuropathic pain: A randomized, double-blind, placebo-controlled phase III study in Asian patients

The present phase III, randomized, double-blind, placebo controlled study evaluated the efficacy, tolerability and safety of mirogabalin, a ligand of the a2d subunit, in Asian patients with DPNP.

Design

Double blind, multicentered, placebo controlled phase III study

Patients

834 Asian patients with DPNP

Treatment

Placebo	Mirogabalin 15 mg/day	Mirogabalin 20 mg/day	Mirogabalin 30 mg/day

Treatment duration

14 Weeks

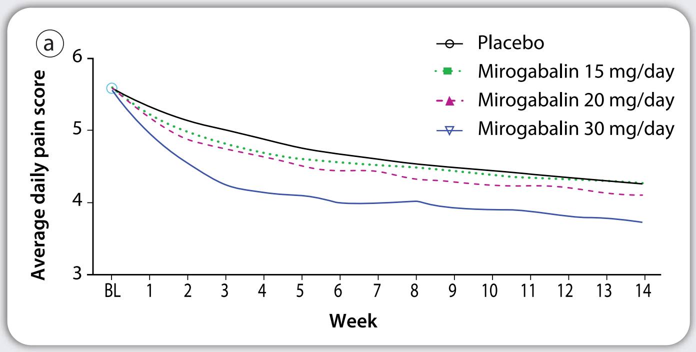

Figure: a. Change in average daily pain score

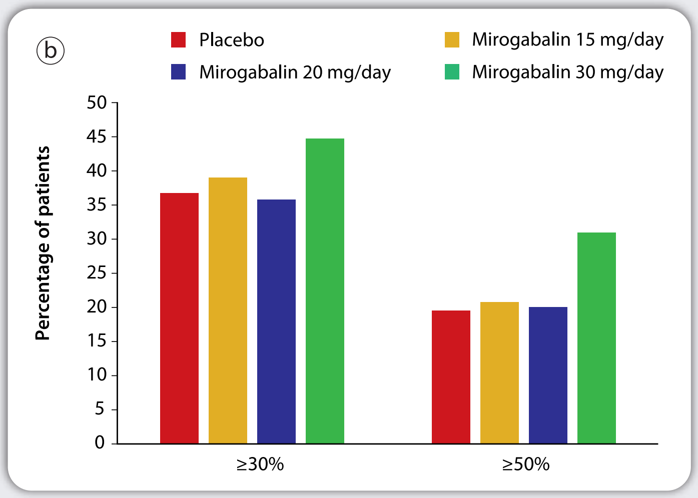

Figure: b. Improvement compared with baseline

Mirogabalin showed dose-dependent efficacy results in Asian patients with DPNP. For the primary endpoint – the change from baseline in ADPS – mirogabalin 30 mg/day results were significantly different than placebo. Mirogabalin was well tolerated up to 30 mg/day. In summary, mirogabalin has a balanced efficacy versus safety profile, and may provide an alternative therapeutic option for the treatment of DPNP.

ABSTRACT

Aims/Introduction

This study evaluated the efficacy and safety of mirogabalin, a novel, potent, selective ligand of the a2d subunit of voltage-dependent Ca2+ channels, for the treatment of diabetic peripheral neuropathic pain (DPNP).

Materials and Methods

During this double-blind, multisite, placebo-controlled phase III study, Asian patients aged ≥20 years with type 1 or 2 diabetes and DPNP were randomized 2:1:1:1 to a placebo, mirogabalin 15, 20 or 30 mg/day for up to 14 weeks, with a 1- to 2-week titration (NCT02318706). The primary endpoint was the change from baseline in average daily pain score (ADPS) at week 14, defined as a weekly average of daily pain (0 = no pain to 10 = worst possible pain, for the past 24 h).

Results

Of 834 randomized patients, 330, 164, 165 and 165 received placebo, mirogabalin 15, 20 or 30 mg/day, respectively, and were included in analyses (modified intention-to-treat population, n = 824); 755 (90.5%) completed the study. At week 14, the least squares mean average daily pain score change from baseline was -1.31, -1.34, -1.47 and -1.81, respectively, showing statistical significance for mirogabalin 30 mg/day versus placebo (P=0.0027). The treatment-emergent adverse events observed were mostly mild-tomoderate in all mirogabalin doses, and the most frequent treatment-emergent adverse events were nasopharyngitis, somnolence, dizziness, peripheral edema and weight increase.

Conclusion

Mirogabalin relieved DPNP in a dose-dependent manner; mirogabalin 30 mg/day showed statistically significant pain relief (vs placebo) in Asian DPNP patients. All doses of mirogabalin tested were well tolerated.

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