

Milnacipran Improves Pain, PGIC, Physical Function, and Depressive Symptoms in Fibromyalgia: Results From a Placebo-Controlled Milnacipran Trial

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Purpose

The management of fibromyalgia (FM) is complicated by multiple symptoms, including pain, fatigue, stiffness, physical dysfunction, and depressive symptoms. Milnacipran is a serotonin and norepinephrine reuptake inhibitor approved in the US for the management of FM. This clinical trial evaluated the effect of milnacipran 100 mg/day in FM patients on the multidimensional symptoms of FM, including depressive symptoms.

Method

In this phase 3 trial, FM patients were randomized to milnacipran 100 mg/day (n=516) or placebo (n=509) for 12 weeks of stable-dose treatment. Primary endpoints included 2 composite responder analyses. A 2-measure analysis required individual patients to have $\geq 30\%$ improvement from baseline in pain VAS scores and a rating of "much improved" or "very much improved" on the Patient Global of Impression of Change (PGIC); a 3-measure analysis also required a ≥ 6 -point improvement in the SF-36 Physical Component Summary score. Depressive symptoms were assessed by using the Beck Depression Inventory (BDI).

Results

Treatment with milnacipran vs placebo resulted in a significantly higher proportion of composite responders (2-measure: 42% vs 26%; 3-measure 30% vs 16%; both $P < .001$). At endpoint, LS mean changes from baseline in BDI scores were significantly greater with milnacipran vs placebo (-2.12 vs -1.24; $P = .008$). In a post hoc analysis, small but statistically significant correlations were found between changes in BDI in the milnacipran group and changes in pain VAS ($r = 0.210$) and PGIC ($r = 0.309$) (both $P < .001$). However, pain and PGIC scores improved regardless of changes in BDI. The most common adverse event was nausea.

Conclusions

In FM patients, treatment with milnacipran 100 mg/day significantly improves multiple domains, including pain, global status, physical function, and depressive symptoms.