Efficacy of mirtazapine for the treatment of fibromyalgia without concomitant depression: A randomized, double-blind, placebo-controlled phase IIa study in Japan.

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Abstract

To evaluate the efficacy and safety of mirtazapine in Japanese patients with fibromyalgia (FM), a parallel-group, randomized, double-blind, placebo-controlled phase IIa study was conducted at 57 sites between November 2012 and February 2014.

Patients aged 20-64 years who met the American College of Rheumatology 1990 diagnostic FM criteria and had stably high pain scores during a placebo run-in period were randomly assigned (1:1) by a computer-generated allocation sequence (block size 4) to receive mirtazapine orally (15 mg/day for 1 week and then 30 mg/day) or matching placebo for 12 weeks.

The primary endpoint was change in mean numerical rating scale (NRS) pain score from baseline to endpoint (Week 12 or early discontinuation).

Of 430 patients randomized (n=215 each group), 422 (n=211 each group) were analyzed for the primary endpoint.At the study endpoint, mirtazapine caused a significantly greater reduction in the mean NRS pain score compared with placebo (difference 0.44; 95% confidence interval, -0.72 to -0.17; p=0.0018).

The reduction by mirtazapine remained significantly greater compared with placebo from Week 6 onward.

More patients treated with mirtazapine had their NRS pain score reduced by ≥30% from baseline (45.5% vs 30.8%).

Mirtazapine also improved pain-related quality of life assessed by the Japanese version of the Fibromyalgia Impact Questionnaire and the Short-Form 36 Questionnaire.

Adverse events were more common with mirtazapine than placebo (68.8% vs 56.7%), including somnolence (32.1% vs 7.4%), weight gain (17.7% vs 0.9%), and increased appetite (11.6% vs 3.3%).

In conclusion, mirtazapine was an effective and safe treatment for Japanese FM patients.

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