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# Efficacy and safety of mirtazapine in fibromyalgia syndrome patients: a randomized placebo-controlled pilot study.

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## Abstract

**BACKGROUND:** Data from an open-label trial suggest that mirtazapine might prove useful in treatment of fibromyalgia syndrome (FMS).

**OBJECTIVE:** To obtain preliminary efficacy data of mirtazapine for estimation of sample size requirements for a Phase 2 clinical trial in FMS.

**METHODS:** This 13-week randomized controlled trial compared the effects of mirtazapine 15 mg/day, mirtazapine 30 mg/day, and placebo in 40 patients with FMS. The primary outcomes were change in Pain Visual Analog Scale (PVAS) and proportion of pain responders (≥30% PVAS reduction). Secondary outcomes included scores from the Jenkins Sleep Scale (JSS), Patient Global Impression of Change (PGIC), Fibromyalgia Impact Questionnaire (FIQ), Hamilton Depression Rating Scale (HAM-D), Patient Global Assessment, and self-reported adverse events.

**RESULTS:** Significant within-group PVAS reductions from baseline were observed in all 3 groups, with the greatest improvement in the mirtazapine 30-mg group ($p < 0.005$); between-group difference was not significant. The proportion of pain responders did not meet significance criteria (66.67% for mirtazapine 30 mg, 50% for mirtazapine 15 mg, 41.67% for placebo). Significant within-group improvement in JSS scores was seen for mirtazapine 30 mg ($p < 0.01$) and mirtazapine 15 mg ($p < 0.05$). Between-group comparison achieved significance for JSS item 3, waking several times per night ($p < 0.05$). On the PGIC, 72.73% felt better with both mirtazapine dosages compared with 50% for placebo. Within-group FIQ responses indicated improvement in only mirtazapine-treated groups, whereas within-group improvement for HAM-D and Patient Global Assessment was observed in all groups. Based on our findings, the sample size requirement (80% power, 5% type I error) should be 83 per group to detect PVAS change difference between mirtazapine 30 mg and placebo. Common mirtazapine-related adverse events were increased appetite and weight gain.

**CONCLUSIONS:** Patients with FMS taking mirtazapine exhibited within-group significant improvement in most of the measured outcomes. Between-group analysis was predictably compromised by the small sample size. Mirtazapine was well tolerated. Further study with a larger sample size is likely to be useful.

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