Efficacy of tramadol in treatment of pain in fibromyalgia.

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Author information

Abstract
An outpatient, randomized, double-blind, placebo-controlled clinical trial was conducted to evaluate the efficacy and safety of tramadol in the treatment of the pain of fibromyalgia syndrome. One hundred patients with fibromyalgia syndrome, (1990 American College of Rheumatology criteria), were enrolled into an open-label phase and treated with tramadol 50-400 mg/day. Patients who tolerated tramadol and perceived benefit were randomized to treatment with tramadol or placebo in the double-blind phase. The primary efficacy outcome measurement was the time (days) to exit from the double-blind phase because of inadequate pain relief, which was reported as the cumulative probability of discontinuing treatment because of inadequate pain relief. One hundred patients entered the open-label phase; 69% tolerated and achieved benefit with tramadol. These patients were then randomized to continue tramadol (n = 35) or convert to a placebo (n = 34) during a 6-week, double-blind treatment period. The Kaplan-Meier estimate of cumulative probability of discontinuing the double blind period because of inadequate pain relief was significantly lower in the tramadol group compared with the placebo group (p = 0.001). Twenty (57.1%) patients in the tramadol group successfully completed the entire double-blind phase compared with nine (27%) in the placebo group (p = .015). These results support the efficacy of tramadol over a period of 6 weeks in a double blind study for the treatment of the pain of fibromyalgia in a group of patients who had been determined to tolerate it and perceive a benefit.

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