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## **Combination of pregabalin with duloxetine for fibromyalgia: A randomized controlled trial.**

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### **Abstract**

Fibromyalgia is a syndrome characterized by chronic widespread pain and associated with sleep disturbance, depression, fatigue and cognitive dysfunction. Polypharmacy is commonly used but supportive evidence is limited. Most fibromyalgia trials focus primarily on pain reduction with monotherapy. This trial compares a pregabalin-duloxetine combination to each monotherapy. Using a randomized, double-blind, four-period crossover design, participants received maximally tolerated doses of placebo, pregabalin, duloxetine and pregabalin-duloxetine combination - for six weeks. Primary outcome was daily pain (0-10); secondary outcomes included global pain relief, Fibromyalgia Impact Questionnaire (FIQ), SF-36 survey, MOS sleep scale, Beck Depression Inventory (BDI-II), adverse events and other measures. Of 41 participants randomized, 39 completed  $\geq 2$  treatments. Daily pain during placebo, pregabalin, duloxetine, and combination was 5.1, 5.0, 4.1 and 3.7, respectively ( $p < 0.05$  only for combination versus placebo, and pregabalin). Participants (%) reporting  $\geq$  moderate global pain relief were 18%, 39%, 42% and 68%, respectively ( $p < 0.05$  for combination versus placebo, pregabalin, and duloxetine). FIQ scores were 42.9, 37.4, 36.0 and 29.8, respectively ( $p < 0.05$  for combination versus placebo, pregabalin, and duloxetine). SF-36 scores were 50.2, 55.7, 56.0 and 61.2, respectively ( $p < 0.05$  for combination versus placebo, pregabalin, and duloxetine). MOS Sleep scores were 48.9, 35.2, 46.1 and 32.1, respectively ( $p < 0.05$  only for combination versus placebo, and duloxetine). BDI-II scores were 11.9, 9.9, 10.7 and 8.9, respectively ( $p < 0.05$  only for combination versus placebo). Moderate-severe drowsiness was more frequent during combination versus placebo. Combining pregabalin and duloxetine for fibromyalgia improves multiple clinical outcomes versus monotherapy. Continued research should compare this and other combinations to monotherapy for fibromyalgia.

### **SUMMARY:**

This double-blind randomized controlled trial demonstrates improved outcomes with a pregabalin-duloxetine combination over either single drug for fibromyalgia.