

Rapid Antimanic effect of Risperidone: A 3-week, double-blind, placebo-controlled trial
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Objective: To evaluate the efficacy and tolerability of flexible doses of risperidone in acute bipolar mania.

Methods: For 3 weeks, 279 patients in an acute manic episode of bipolar I disorder received 1–6 mg/day of risperidone. Efficacy was measured as change from baseline to treatment endpoint in Young Mania Rating Scale (YMRS) scores.

Results: The trial was completed by 56% of the 125 patients in the risperidone group, and 42% of the 134 patients in the placebo group. The mean modal dose of risperidone was 4.1 mg/day. Improvements in YMRS scores were significantly greater in the risperidone than placebo group at endpoint (-11.1 ± 0.9 vs -5.0 ± 0.9 ; $p < 0.001$). Significant between-group differences in change scores were seen as early as 3 days after start of treatment (risperidone, -6.9 ± 0.6 ; placebo, -4.3 ± 0.5 ; $p < 0.001$) and at weeks 1, 2, and 3. The most common adverse event reported by patients receiving risperidone was somnolence (28%).

Conclusion: Risperidone was efficacious and well tolerated in the treatment of patients with acute bipolar mania, with a rapid onset of action seen as early as day 3.