

Risperidone Monotherapy in Acute Bipolar Mania

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Objective: To evaluate risperidone as monotherapy in acute mania.

Methods: In a multiphase, 12-week, randomised, double-blind, (placebo-controlled trial, 3 weeks), patients with acute manic episodes received flexible doses of risperidone (1– 6 mg/day), haloperidol (2-12mg/day), or placebo. In the second phase, subjects could continue on either double-blind risperidone or haloperidol, or open-label risperidone. Placebo patients continuing on double-blind medication received risperidone. Efficacy was measured as change from baseline to endpoint in Young Mania Rating Scale (YMRS) scores. Subjects had a baseline YMRS score ≥ 20 .

Results: Of 438 patients, 154 were randomised to risperidone, 144 to haloperidol and 140 to placebo. Mean baseline YMRS scores were 32.1, 31.3, 31.5 for risperidone, haloperidol and placebo respectively. Mean modal dose of risperidone and haloperidol were 4.2 and 8.0 mg/day, respectively. After 3 weeks, mean change from baseline was -15.1 ($p < 0.001$), -13.9 ($p < 0.001$), and -9.4 , for risperidone, haloperidol and placebo, respectively. Further, 227 patients entered the 9-week double-blind continuation phase. Change from baseline YMRS at 12 weeks was -18.6 and -17.2 for risperidone and haloperidol, respectively. There were no unexpected adverse events, with extrapyramidal disorder and hyperkinesia most common with haloperidol, and to a much lesser extent with risperidone.

Conclusion: Risperidone monotherapy is efficacious and well tolerated in the 12-week treatment of acute mania.