

Risperidone Monotherapy in Acute Bipolar Mania: A 9-Week Extension Trial of Patients in US Sites

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Purpose: To examine the safety and efficacy of risperidone monotherapy in a 9-week, US-based, open-label extension trial of patients with bipolar I disorder.

Methods: This was a 9-week, open-label extension study of a 3-week, placebo-controlled monotherapy trial in which patients received flexible (1 to 6 mg/day) doses of risperidone for the treatment of acute mania. Patients who entered this open-label extension study were enrolled at study sites in the United States. Risperidone was administered in flexible doses, starting at 3 mg/day. The Young Mania Rating Scale (YMRS) was the primary efficacy measurement. Additional measures were the Clinical Global Impressions-Severity scale, Global Assessment Scale, Positive and Negative Syndrome Scale, and the Extrapyramidal Symptom Rating Scale (ESRS).

Results: Of the 83 patients who entered the extension study, 45 had previously received risperidone (RIS/RIS) in the acute treatment trial and 38 had received placebo (PLA/RIS). The study was completed by 60% of patients, and a total of 72 were included in the intent-to-treat population for efficacy assessments. The mean modal dose (SD) of risperidone was 3.5 (1.4) mg/day. In the group continuing on risperidone (RIS/RIS), the YMRS total score decreased from 10.3 (6.9) at entry to 8.2 (8.1) at endpoint ($P = 0.038$). Risperidone was well tolerated. There was a slight increase in mean weight of 0.4 kg in the RIS/RIS group. The ESRS total score decreased slightly from 1.2 (2.3) at baseline to 1.1 (2.1) at endpoint in the RIS/RIS group. In the group that was switched from placebo to risperidone (PLA/RIS), the YMRS total score decreased from 14.4 (7.5) at entry to 6.5 (6.6) at endpoint ($P < 0.001$). Risperidone was well tolerated. There was a slight increase in mean weight of 0.1 kg from baseline to endpoint in the PLA/RIS group. The ESRS total score increased slightly from 1.0 (2.6) at baseline to 1.4 (3.0) at endpoint in the PLA/RIS group.

Conclusion: Risperidone treatment was well tolerated and resulted in additional improvement during the 9-week extension. Patients switched from placebo to risperidone improved markedly.

References:

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