Janssen Research & Development

Clinical Research Report
Protocol RIS-INT-3

R-64766 (Risperidone)

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ABSTRACT

A randomized, double-blind, placebo-controlled multicenter study compared four fixed doses of risperidone and one dose of haloperidol in schizophrenic patients. Patients were treated for eight weeks with risperidone 2, 6, 10, or 16 mg, haloperidol 20 mg, or placebo. During the first week of double-blind treatment period, fixed upward titration was required to reach the maximal dose within each treatment group. The primary measures of effectiveness were: the total score of the Positive and Negative Syndrome Scale (PANSS) for schizophrenia and clinical improvement, defined a priori as 20% or greater reduction from baseline of the total PANSS score.

All four doses of risperidone improved psychotic symptoms. At endpoint, patients receiving risperidone 2, 6, 10, and 16 mg showed significant reduction from baseline compared to placebo in the total PANSS score and clinical improvement. Although significant improvement was shown with all doses of risperidone compared to placebo, the 6 mg group demonstrated the greatest improvement. Risperidone 6 mg was also more effective than haloperidol 20 mg in all efficacy variables. The incidence of extrapyramidal symptoms (EPS) in the risperidone 2 and 6 mg groups, as determined by patient-elicited complaints, the Extrapyramidal Symptoms Rating Scale (ESRS), or amount of EPS medication used, was similar to placebo. The occurrence of EPS increased with higher doses of risperidone but less than haloperidol. No clinically significant differences among treatment groups were detected with respect to ECG or laboratory tests, except for a dosis proportional increase in plasma prolactin levels.