



ABSTRACT

A randomized, double-blind, placebo-controlled multicenter study compared risperidone and haloperidol in schizophrenic patients. Patients were treated for six weeks with risperidone (N=53), haloperidol (N=53), or placebo (N=54). Patients received one tablet (1 mg for risperidone and 2 mg for haloperidol) at the start of the study and the dose could be increased during the first two weeks of the double-blind treatment in one-tablet increments, depending on response. The maximal dose was 10 tablets (10 mg risperidone or 20 mg haloperidol). The primary measures of effectiveness were: the total score of the BPRS, clinical improvement, defined a priori as 20% reduction from baseline of the total BPRS score, and CGI-severity of schizophrenia.

Risperidone significantly improved psychotic symptoms compared to placebo for the total BPRS score and clinical improvement. The CGI-severity of schizophrenia for the risperidone group was marginally significant compared to placebo at endpoint. The incidence of adverse experiences in the risperidone group was similar to the placebo group. The risperidone-treated patients had no greater incidence of EPS than placebo and took less EPS medication compared to haloperidol-treated patients. Laboratory testing revealed no clinically significant differences between treatment groups.