RISPERIDONE VERSUS HALOPERIDOL IN THE TREATMENT OF CHRONIC SCHIZOPHRENIC PATIENTS : A PARALLEL GROUP DOUBLE-BLIND COMPARATIVE TRIAL.

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A parallel group double-blind comparative trial was conducted to study the clinical efficacy and safety of risperidone.

After a one-week single-blind placebo wash-out, 35 chronic schizophrenic patients (DSM-III-R) (17 male, 18 female) were randomly assigned to one of two groups for eight weeks of double-blind treatment. After 2 week of initial dose of 2.5mg b.i.d., the dose could be increased to 5 mg b.i.d. in case of insufficient response. On days -7, 0, 7, 14, 28, 42, and 56, the patients' psychopathology was assessed by means of the Positive and Negative Syndrome Scale for Schizophrenia (PANSS) and the Clinical Global Impression(CGI). Safety assessments included the Extrapyramidal Symptom Rating Scale (ESRS), the UKU Side Effect Rating Scale.

Thirty-two patients completed the trial. The the mean changes from baseline on the total PANSS score, on the total BPRS score and CGI score were comparable in both treatment groups. The number of patients where a clinical improvement was seen was also similar in both treatment groups. Risperidone caused less extrapyramidal symptoms. No significant changes in ECG, vital signs, body weight, and clinical laboratory tests were induced.

This study has demonstrated that the combined serotonin 5-HT_2 and dopamine-D_2 antagonist risperidone is an antipsychotic as potent as halperidol. Risperidone causes less extrapyramidal symptoms, and is better tolerated than haloperidol.