

Long term treatment of schizophrenia with risperdal : An international multicenter open label trial

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This open multicenter international trial was designed to investigate the efficacy and safety of risperidone administered once daily during seven months in subjects with an acute exacerbation of chronic or sub-chronic schizophrenia. It was conducted in ten countries (Cyprus, Egypt, Gulf, Pakistan, Saudi Arabia, Iran, Jordan, Lebanon, Syria and Turkey). The subject's psychopathology was assessed by the PANSS and the clinical response was defined as a reduction of >20% on the total PANSS score compared with baseline. Secondary parameters were the shift between endpoint and baseline of the PANSS subscales, total BPRS and clusters score and the clinical global impression (CGI). Quality of life (QOL) was assessed using the SF-12 questionnaire. Safety evaluation included laboratory analysis (blood biochemistry and hematology, urine analysis), ESR assessments, ECG and vital signs (weight, blood pressure and heart rate). A total of 809 out of 819 of the males was included in the safety analysis and 797 in the ITT efficacy analysis. The mean daily dose of risperidone averaged 5.9 mg. Early study termination occurred in 22.6% of the subjects, of whom 3.1% were due to adverse events (AEs). Clinical response was seen in 86% of the subjects at endpoint. A 58% clinical improvement in total PANSS was also observed. Negative and positive PANSS sub- scales improved by 54% and 64%, respectively. The clinical improvement on total BPRS was 58.7% at endpoint. Based on the CGI, 87% of the subjects experienced an improvement of their condition compared with baseline and 9% remained unchanged. These data showed that risperidone administered once daily at a mean dose of 5.9 mg/day for up to seven months significantly reduced the severity of acute exacerbation in subjects with chronic or sub-chronic schizophrenia with an overall good safety profile.