AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel XR and Risperdal
ACTIVE INGREDIENT: Quetiapine Prolong and Oral Risperidone

Study No: D1443L00042
A Pilot Study of Three-Week, Randomised, Open Comparison in Schizophrenic In-patients Treated with Quetiapine Prolong or Oral Risperidone at Flexible Dose

Developmental phase: IIIb
Study Completion Date: 5.12.2008
Date of Report: 19.11.2009

OBJECTIVES:

This pilot trial in Finland was designed to evaluate in a randomized fashion change of agitation in acute schizophrenic patients (Schizophrenia or Schizoaffective psychosis or Schizophreniformic psychosis) (DSM - IV) with the first visits on days 1, 2, 4 or 5 and 7 ± 1.

Primary objective was a change from baseline in PANSS-EC score.

Secondary objectives were change from baseline in CGI-S and absolute CGI-I scale, change from baseline in OAS scale and change from baseline in total PANSS score.

METHODS:

This was an open-label, active-reference-controlled, randomised, multi-centre, phase IIIb pilot study of three-weeks. Four sites were participating in the study. Two sites recruited patients. Patients who met the eligibility criteria were randomised to one of two treatment regimens to receive either Quetiapine Prolong or Risperidone in ratio 1:1. It was planned to include 15 subjects in both treatment regimens, but only 3 subjects were randomised. This was a pilot study and the sample size was not based on statistical calculations. Due to the small patient number no efficacy results can be drawn from this pilot study.

RESULTS:

Summary of efficacy results

The aim of the study was to assess efficacy of Quetiapine prolong in comparison to risperidone using rating scales to document changes of the mental status of a subject. Because only two patients completed the study, no efficacy results can be presented.

Summary of safety results

No SAEs were reported during the study. Subject 03-01 had reported vomiting and muscle spasms in the legs, which the Investigator evaluated with positive causality. At visit 6 an elevated prolactin level was detected for subject 03-01, this was also reported as an adverse event with positive causality. In other laboratory assessments no clinically significant values were observed. No EPS were observed with BARS and SAS.