

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: Seroquel

ACTIVE INGREDIENT: Quetiapine

Study No: NIS-NKR-SER-2008/1

Atypical antipsychotics in improvement of quality of life in Bipolar disorder -
POLE study

Developmental phase: Marketed

Study Completion Date: 2008-11-19

Date of Report: 2009-11-04

OBJECTIVES: The primary objective of this survey is to determine the improvement of 8-week treatment with atypical antipsychotics in patients' quality of life with Bipolar disorder in a real clinical practice. The secondary objective is to assess the efficacy of atypical antipsychotics on bipolar patients.

METHODS:

This study was non-interventional, prospective, multi-center study.

The study will include adult (ages 18 to 65 years) both sexes, diagnosed as bipolar disorder (bipolar I disorder, bipolar II disorder) according to DSM-IV-TR criteria, who will be prescribed open-label flexible dose of atypical antipsychotics by clinical decision.

RESULTS:

Total 965 patients were enrolled in this study. Among them, the efficacy in 786 patients were evaluated .

The mean score of Q-LES-Q SF increased from 46.50 ± 10.33 at 1st visit to 53.11 ± 8.90 at 2nd visit and it is suggested that quality of life improved after treatment ($p < .0001$). The QoL of total 16 sub-classifications advanced significantly and it showed that the QoL improvement was relatively large in the classifications of social relationships and family relationship.

As a result of Clinical global impression-BP version in overall bipolar illness, overall symptom was improved as declining mean score by 0.80 ± 1.22 from 2.84 ± 1.40 at 1st visit to 2.04 ± 0.91 at 2nd visit ($p < .0001$). As a result of the assessment in mania, mean score decreased by 0.77 ± 1.17 from 2.65 ± 1.45 at 1st visit to 1.88 ± 0.92 at 2nd visit. So it was analyzed that the symptom improved ($p < .0$

001). In terms of depression, mean score decreased by 0.32 ± 0.99 from 2.08 ± 1.21 to 1.76 ± 0.84 ($p < .0001$).

The mean GAF score increased by 8.09 ± 11.83 from 61.89 ± 16.39 at 1st visit to 69.98 ± 13.34 at 2nd visit, which means the condition of patients improved ($p < .0001$).

