AstraZeneca

STUDY REPORT SUMMARY

Study data show that following 6 months of therapy with atypical antipsychotic agents once daily the functioning of patients with schizophrenia improved in comparison to study entry.

ASTRAZENECAPHARMACEUTICALS

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FINISHED PRODUCT:
Seroquel SR

ACTIVE INGREDIENT:
quetiapine

Study No:
NIS-NSI-SER-2008/1 (NCT00833456)

Developmental phase: Non-interventional study

Study Completion Date: July 2011

Date of Report: October 2011

OBJECTIVES:

Primary Objective:
The primary objective of the study is to compare improvement in global assessment of functioning (using the GAF scale) between the baseline and the final study visit in the Seroquel SR-treated group.

Secondary Objective:
The main secondary objective is to assess improvement in global assessment of functioning (using the GAF scale) between the baseline and the final study visit in the group of patients treated with other atypical antipsychotics.
Other secondary objectives (for both treatment groups) include assessment of other measures of clinical improvement, evaluation of compliance and of adverse effects

METHODS:

Patient population

Patients eligible for entry into the study, male and females, will have a diagnosis of schizophrenia, as defined by DSM-IV-TR and their symptoms are controlled with Seroquel SR started up to 1 month before the inclusion or other atypical antipsychotic in once daily formulation started up to 1 month before the inclusion.
Age limitation is set between 18 and 80 years.
All eligible patients will be included in the protocol provided they will receive detailed information in advance and will sign consent to grant access to their own data collected during this program. (See attached Inform Consent Form)
All included patients should be treated according to the SmPC

Design

The study will be performed by the guidelines for antipsychotic medication prescription. To diminish inclusion bias only patients already receiving Seroquel SR for up to one month will be included and patients already switched to another once daily atypical antipsychotic in one month period will be included.

NIS will be conducted as an open-label non-randomised follow-up study involving patients with schizophrenia receiving Seroquel SR and patients already switched to another once daily atypical antipsychotic in one month period will be included at the discretion of the treating physician, in accordance with the current treatment guidelines and the patient's clinical status.

All the patients will be followed for 6-month period. In this period all the data for study protocol will be collected.
As the NIS is observational, the basic methodological assumption is that it monitors a single population.
All patients will be treated according to the current label, within the approved dose range of Seroquel SR or another once daily atypical antipsychotic.

Study plan

Patient will be included in the study during the routine examination by the researcher, after Written consent for data review and processing will be signed and when inclusion and exclusion criteria will be met. Patient will be informed about the possibility that on his demand he could be excluded from the study at any time. However, reasons for this demand should be provided to psychiatrist and recorded.

Event	First visit Week 0	Second visit Week 12 ±2	Third visit Week 24±2
Inclusion / exclusion criteria, collection of demographic data	X		
Doctors assessment of patients adherence to current antipsychotic medication		X	X
Doctors assessment of patients adherence to previous antipsychotic medication	X		
Calculation of number of tablets in		X	X

possession			
Adverse events evaluation form	X	X	X
CGI	X	X	X
GAF	X	X	X
Concomitant medication	X	X	X

Study Drug
Seroquel SR or another once daily atypical antipsychotic.

Statistical analysis
Primary objective
The null hypothesis will be the one of no improvement in global assessment of functioning in the Seroquel SR-treated group between the beginning and the end of the study period. The hypothesis will be tested using paired t-test or, in case of exceedingly skewed distribution of results, using the appropriate non-parametric analysis (paired Wilcoxon test). The hypothesis will be tested at a significance level of 0.05.

Secondary objectives
Secondary objectives will include analysis global assessment of functioning improvement in the other treatment group, as well as analyses of treatment adherence/compliance and adverse effects incidences in both treatment groups. Descriptive statistics will be employed. Additional non-inferential post-hoc testing may be performed with these data.

Sample size calculation:
Under the assumption of a 20% drop-out rate, the total number of 500 subjects would yield the sample size of 200 subjects per treatment group. With the significance level of 0.05 and power of 0.80, this number of subjects would allow to detect a true mean within-individual difference of only 2 GAF points assuming GAF score SD of 12. Thus, sample size is completely sufficient.

RESULTS:

Background: The diagnosis of schizophrenia can only be made when the mental disorder (beside fulfilling other criteria) also affects person's functioning in the areas such as employment, independent living and social functioning. The purpose of the present study was to monitor changes in the global functioning of patients with schizophrenia treated with atypical antipsychotic agents once daily for 6 months.
Methods: Global functioning of patients was evaluated using the GAF (Global Assessment of Functioning) scale. The total sample included 116 patients with schizophrenia. 77% (n = 89) met the inclusion criteria; 53% (n = 62) have been receiving prolonged-release quetiapine therapy and 23% (n = 27) have been receiving other antipsychotic agents.
Results: About a half of the enrolled patients were female. The mean age of the patients was 41.12 years (SD 12.36 years) and was slightly higher in the quetiapine group than in the group receiving other antipsychotic agents (44.46 years [SD 11.85 years] vs. 35.7 years [SD 12.2 years], respectively). In the quetiapine group the mean GAF value following 6 month of therapy was 68.5 points (SD 14.6) and was 19.3 points higher vs. the baseline GAF value. In the quetiapine group, the mean value at the last visit was 67.5

points (SD 49.4) and was 18.04 points higher vs. the baseline value. No significant changes were found between treatment groups.
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Adverse event
Adverse event reporting was conducted in line with the requirements of the Rules of the pharmacovigilance of medicinal products for human use (Official Gazette of the Republic of Slovenia, Nr. 53/2006).