Clinical Study Results Posting Template

Template completed by:	**Name: Irene Kop**	**Signature:**
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Posting Results:

☐ Study in patients with a serious or life-threatening disease or condition

☒ Hypothesis-testing study in any indication

☐ Non-interventional study with an approved AZ medicine

1. Titles and Background Information

- Protocol ID: D1441C00003
- Secondary ID:
- Official Title: The effect of quetiapine on psychotic-like symptoms in borderline personality disordered patients. A randomized placebo-controlled trial.
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- Finished Product: quetiapine
- Active Ingredient: quetiapine fumarate
- Study Phase: Phase 3
- Study Status: Completed
- Condition/Disease: Borderline disorder

2. Key Study Dates

- Study Start Date: 12-Feb-04
- LSLV Date: 26-Jun-07

- Database Lock: 30-Jan-08
- Approval Date: 27-Jan-03

3. Objectives

To explore the effect of quetiapine on psychotic-like symptoms and on severity of other psychiatric symptoms like depression, anger, impulsiveness, hostility and anxiety in patients with BPD and psychotic-like symptoms, in comparison with placebo treatment.

4. Methods

24 patients were randomly assigned to quetiapine (n=13) or placebo (n=11). Diagnoses were made using the Structured Clinical Interview for DSM-IV Axis II Personality Disorders (SCID II). Patients with schizophrenia, current major depression, bipolar disorder or substance dependence were excluded. Quetiapine dosage was flexible, the dose range was 200 to 600 mg/day, with most patients receiving 400 mg/day for a period of 8 weeks. No concomitant psychotropic medication was allowed, except for SSRI's and benzodiazepines, with doses stabilized 8 weeks before start of the study period. Patients were assessed at baseline and at 1, 2, 4, 6 and 8 weeks of treatment. There was a follow up assessment in week 10. The primary outcome measures were scores on the Brief Psychiatric Rating Scale (BPRS), Positive and Negative Symptoms Scale (PANSS) and the Dissociation Questionnaire (DIS-Q).

5. Results

Quetiapine was significantly superior to placebo on the BPRS total score and PANSS general psychopathology scale in mixed model analysis. The interaction effects between drug group and time were significant (BPRS: $F(3,48) = 3,1$, $p < 0,05$, PANSS general psychopathology: $F(3,48) = 5,22$, $p < 0,01$). Scores at endpoint (week 8) also showed significantly superior results for the quetiapine group on both these scales ($p < 0,01$). The DIS-Q showed no significant differences. Dropout before week 8 was comparable between the two groups (quetiapine: 5 subjects, placebo: 3 subjects).

6. Reference : Select from list

Citation:

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