Article: EPA-1552
Topic: P31 - Schizophrenia

FLEXIBLY DOSED PALIPERIDONE PALMITATE IN NON-ACUTE BUT SYMPTOMATIC PATIENTS WITH SCHIZOPHRENIA PREVIOUSLY UNSUCCESSFULLY TREATED WITH LONG-ACTING INJECTABLE RISPERIDONE

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Introduction: To explore tolerability, safety and treatment response of flexibly dosed paliperidone palmitate (PP) in adult non-acute but symptomatic patients with schizophrenia previously unsuccessfully treated with risperidone long-acting injectable treatment (RLAT).

METHODS: International, prospective 6-month open-label study. Major outcomes were clinical response (percentage of patients with ≥20% improvement in Positive and Negative Syndrome Scale (PANSS) total score at endpoint), functioning (Personal and Social Performance scale (PSP)), Extrapyramidal Symptom Rating Scale (ESRS), sleep quality, daytime drowsiness and treatment-emergent adverse events (TEAEs).

RESULTS: The intent-to-treat population comprised 56 patients (64.3% male, mean age 39.9±11.0 years, 71.4% paranoid schizophrenia). 71.4% of patients completed the 6-month study. Withdrawal of consent (8.9%) and adverse events (10.7%) were the most frequent reasons for early discontinuation. Mean PANSS baseline total score was 67.5±20.7 and decreased by -9.2 points at endpoint (95% confidence interval -15.0;-3.5, p<0.0001). At endpoint, 61.1% of patients had improved by ≥20% in PANSS total score. Patient functioning in PSP increased by 5.2±15.3 points (p=0.0163). Sleep quality and daytime drowsiness improved significantly (both p<0.0292). Extrapyramidal symptoms in ESRS significantly improved from 3.7±7.2 at baseline to 2.4±6.4 at endpoint (p=0.0011). TEAEs reported in ≥5% were psychotic disorder (10.7%), injection site pain, headache, schizophrenia, anxiety (7.1% each), constipation and somnolence (5.4% each). Mean body weight decreased by 0.9±4.5 kg from baseline to endpoint.

Conclusion: These data suggest that paliperidone palmitate is associated with a meaningful clinical response and functional improvement and is well tolerated with less EPS in non-acute, symptomatic schizophrenia patients previously unsuccessfully treated with RLAT.

https://doi.org/10.1016/S0924-9338(14)78716-4 Published online by Cambridge University Press