Methods. In the 25-week, double-blind ALPINE study, adults hospitalized for an acute exacerbation of schizophrenia were randomized to AL (AL NanoCrystal Dispersion + oral aripiprazole 30 mg day 1; AL 1064 mg day 8 and q8wk) or the active control paliperidone palmitate (PP 234 mg day 1; PP 156 mg day 8 and q4wk), discharged after 2 weeks if clinically stable, and followed through the end of the study. Adverse events, including adverse events of special interest (AESIs; extrapyramidal symptoms [identified by non-mutually exclusive standardized MedDRA queries], sedation, hypotension, injection site reactions [ISRs], suicidal ideation and behavior) were monitored throughout the study.
Results. In total, 200 patients were randomized (AL, n=99; PP, n=101); 99 patients (AL, n= 56; PP, n=43) completed the study. Rates of AESIs in AL-treated patients were akathisia, 10%; Parkinson-like events, 2%; dyskinesia, 3%; dystonia, 9%; sedation, 7%; hypotension, 6%; ISRs, 18 % (including placebo); and suicidal ideation and behavior, 2 %. In PP-treated patients, AESI rates were akathisia, 12%; Parkinson-like events, 4%; dyskinesia, 5%; dystonia, 11%; sedation, 7%; hypotension, 4%; ISRs, 27% (including placebo); and suicidal ideation and behavior, 3%.
Conclusion(s). No unexpected safety and tolerability findings were identified in patients treated with AL or PP who were hospitalized for acute schizophrenia exacerbation and transitioned to outpatient care in ALPINE. AESI profiles were consistent with each treatment's respective known safety profile.
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Minimal Clinically Important Difference in AIMS Score Based on CGIC and PGIC in Patients With Tardive Dyskinesia Treated With Deutetrabenazine

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Abstract

Background. Deutetrabenazine is FDA approved for tardive dyskinesia (TD) based on two 12-week, placebo-controlled studies evaluating safety and efficacy in patients with baseline Abnormal Involuntary Movement Scale (AIMS) score ≥6. Deutetrabenazine reduced overall AIMS scores compared with placebo in ARM-TD (–3.0 vs –1.6, P=0.019) and AIM-TD (24 mg/day, –3.2 vs –1.4, P=0.003; 36 mg/day, –3.3 vs –1.4, P=0.001). This analysis assessed Minimal Clinically Important Difference (MCID) in AIMS score in patients with TD treated with deutetrabenazine.
Methods. MCID is the smallest change from baseline in AIMS score that is meaningful for patients. MCID analyses were performed based on Patient Global Impression of Change (PGIC) and Clinical Global Impression of Change (CGIC) as anchors described by Hauser et al., where MCID is the difference between patients treated with deutetrabenazine who were minimally improved and patients treated with placebo who were unchanged. Additional MCID definitions were explored: difference between patients who demonstrated treatment improvement versus those who did not (Method 2); difference between patients who demonstrated treatment success versus those who did not (Method 3).
Results. 295 patients were analyzed. Based on PGIC, the suggested MCID was –2.8. Results were similar for Method 2 (75% of patients had treatment improvement; MCID = –2.8) and Method 3 (38% of patients had treatment success; MCID = –2.6). Based on CGIC, the suggested MCID was –2.6. Results were similar for Method 2 (76% of patients had treatment improvement; MCID = –2.8) and Method 3 (41% of patients had treatment success; MCID = –3.0). Therefore, the suggested MCID for deutetrabenazine is –3.
Conclusions. The MCID for change in AIMS score based on PGIC and CGIC for deutetrabenazine was –3 regardless of the analytical method. Findings suggest an AIMS score reduction of ~3 is associated with clinically meaningful improvement in TD symptoms.
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Effect of Deutetrabenazine on Metabolic Parameters in the Treatment of Tardive Dyskinesia

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Abstract

Background. Deutetrabenazine, a novel vesicular monoamine transporter 2 (VMAT2) inhibitor, is approved by the FDA for treatment of tardive dyskinesia (TD) in adults. Dopamine-receptor antagonists (DRAs) are associated with worsening of metabolic parameters, including weight gain, hyperlipidemia, and elevated blood glucose. This post hoc analysis assessed the short-

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