P-339 - EFFECT OF LISDEXAMFETAMINE DIMESYLATE ON FUNCTIONAL IMPAIRMENT IN CHILDREN AND ADOLESCENTS WITH ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

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Introduction: Lisdexamfetamine dimesylate (LDX) is the first long-acting, prodrug stimulant, and is approved in the USA, Canada and Brazil for the treatment of attention-deficit/hyperactivity disorder (ADHD).
Objectives and aims: To evaluate the effect of LDX on functional impairment in patients with ADHD, using the Weiss Functional Impairment Rating Scale-Parent (WFIRS-P).
Methods: A randomized, double-blind, placebo-controlled trial of an optimized daily dose of LDX was conducted in children and adolescents (6-17 years) with ADHD in Europe. A 4-week dose-optimization period was followed by 3-weeks of dose-maintenance. The WFIRS-P was completed at baseline, day 28 and endpoint. A decrease from baseline indicated an improvement in functional outcomes. Osmotic-release oral system methylphenidate (OROS-MPH) was included as a reference treatment arm.
Results: Of 336 randomized patients, 317 were included in the full analysis set and 196 completed the study. Baseline mean (SD) WFIRS-P total scores were similar across treatment groups: LDX, 1.01 (0.45); placebo, 1.10 (0.46); OROS-MPH, 1.07 (0.44). The least squares (LS) mean decrease (95% confidence intervals) in WFIRS-P total score from baseline to endpoint was statistically significantly greater with LDX than with placebo (difference of -0.3 [-0.4, -0.2], $p< 0.001$), with an effect size of 0.924 for LDX. The difference in LS mean change from baseline to endpoint between OROS-MPH and placebo was -0.2 (-0.3, -0.1; $p< 0.001$) in favour of OROS-MPH (effect size, 0.772).
Conclusions: LDX was more effective than placebo in improving functional impairments in children and adolescents with ADHD.
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