Randomized, 6-Week, Placebo-Controlled Study of Treatment for Adult Attention-Deficit/Hyperactivity Disorder: Individualized Dosing of Osmotic-Release Oral System (OROS) Methylphenidate With a Goal of Symptom Remission.

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Abstract

OBJECTIVE: To evaluate the efficacy and safety of individualized dosing within the approved dose range for osmotic-release oral system (OROS) methylphenidate hydrochloride in adults with attention-deficit/hyperactivity disorder (ADHD).

METHODS: A double-blind, 6-week trial was conducted between July 2009 and February 2010 at 35 US sites. Adults with ADHD (DSM-IV diagnostic criteria) and a screening ADHD Investigator Symptom Rating Scale (AISRS) score > 24 were randomly assigned to OROS methylphenidate 18 mg or matching placebo. Treatment dose could be increased at 18 mg increments, up to 72 mg/d, until an optimal dose was achieved. AISRS score changes from baseline to end point (primary outcome) were analyzed using analysis of covariance.

RESULTS: At baseline, the intent-to-treat population of 169 OROS methylphenidate and 172 placebo subjects (mean age = 35.8 years) had mean (standard deviation [SD]) AISRS scores of 37.8 (6.94) and 37.0 (7.51), respectively. OROS methylphenidate-treated subjects exhibited a significantly greater mean (SD) AISRS score improvement than placebo subjects (-17.1 [12.44] vs -11.7 [13.30]; P < .001). In general, OROS methylphenidate-treated subjects experienced greater improvements than placebo subjects in secondary measures of symptom frequency, cognitive function, work productivity, and quality-of-life. Little effect of OROS methylphenidate was observed in exploratory sleep assessments. The adverse event pattern was similar to previous reports of stimulants in adults with ADHD.

CONCLUSIONS: OROS methylphenidate treatment with individualized doses titrated to achieve symptom remission demonstrated greater ADHD symptom reduction than placebo treatment. These data support the overall efficacy of OROS methylphenidate treatment in the management of adults with ADHD and provide new possibilities for additional intervention.

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