
Randomized, Double-Blind Trial of Guanfacine Extended Release in Children With Attention-Deficit/Hyperactivity Disorder: Morning or Evening Administration

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Objective

To examine the efficacy and tolerability of guanfacine extended release (GXR) administered in the morning or evening in children with attention-deficit/hyperactivity disorder (ADHD).

Method

In this multicenter, double-blind, placebo-controlled, dose-optimization study, children aged 6–12 years with ADHD were randomized to receive GXR (1–4 mg/d) in the morning and placebo in the evening (GXR am), placebo in the morning and GXR in the evening (GXR pm), or twice daily placebo. The primary efficacy measure was the ADHD Rating Scale-IV (ADHD-RS-IV).

Results

A total of 333 child participants received study drug in the following cohorts: GXR am (n = 107), GXR pm (n = 114), or placebo (n = 112). Mean (standard deviation) changes from baseline to Week 8 (Visit 10 or last observation carried forward) in ADHD-RS-IV total scores were significant for both GXR treatment groups combined (GXR all-active: –20.0 [12.97]) and separately (GXR am: –19.8 [12.95]; GXR pm: –20.1 [13.04]) compared with placebo (–11.0 [12.93]; p <0.001 for all). Most spontaneously-elicited treatment-emergent adverse events were mild or moderate in severity; the most common was somnolence (GXR all-active: 44.3%; GXR am: 46.7%; GXR pm: 42.1%; placebo: 12.5%).

Conclusions

GXR administered either in the morning or evening was associated with significant and clinically meaningful improvements in ADHD symptoms. The levels of response and tolerability observed with GXR were similar regardless of time of dosing (morning vs evening), indicating that once-daily GXR monotherapy is effective whether administered in the morning or evening.

Clinical trial registration information— Tolerability and Efficacy of AM and PM Once Daily Dosing With Extended-release Guanfacine Hydrochloride in Children 6-12 With Attention-Deficit/Hyperactivity Disorder (ADHD) (The ADHD Tempo Study); <http://clinicaltrials.gov/>; NCT00997984.