

Article



Clonidine Extended-Release Tablets as Add-on Therapy to Psychostimulants in Children and Adolescents With ADHD

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ABSTRACT

Objective: To assess the efficacy and safety of clonidine hydrochloride extended-release tablets (CLON-XR) combined with stimulants (ie, methylphenidate or amphetamine) for attention-deficit/hyperactivity disorder (ADHD).

Patients and Methods: In this phase 3, double-blind, placebo-controlled trial, children and adolescents with hyperactive- or combined-subtype ADHD who had an inadequate response to their stable stimulant regimen were randomized to receive CLON-XR or placebo in combination with their baseline stimulant medication. Predefined efficacy measures evaluated change from baseline to week 5. Safety was assessed by spontaneously reported adverse events, vital signs, electrocardiogram recordings, and clinical laboratory values. Improvement from baseline for all efficacy measures was evaluated using analysis of covariance.

Results: Of 198 patients randomized, 102 received CLON-XR plus stimulant and 96 received placebo plus stimulant. At week 5, greater improvement from baseline in ADHD Rating Scale IV (ADHD-RS-IV) total score (95% confidence interval: -7.83 to -1.13; $P = .009$), ADHD-RS-IV hyperactivity and inattention subscale scores ($P = .014$ and $P = .017$, respectively), Conners' Parent Rating Scale scores ($P < .062$), Clinical Global Impression of Severity ($P = .021$), Clinical Global Impression of Improvement ($P = .006$), and Parent Global Assessment ($P = .001$) was observed in the CLON-XR plus stimulant group versus the placebo plus stimulant group. Adverse events and changes in vital signs in the CLON-XR group were generally mild.

Conclusions: The results of this study suggest that CLON-XR in combination with stimulants is useful in reducing ADHD in children and adolescents with partial response to stimulants.

Key Words:

- α_2 -adrenergic agonist
- attention-deficit/hyperactivity disorder
- clonidine-hydrochloride extended-release tablets
- psychostimulant

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