A randomized, double-blind, cross-over, phase IV trial of oros-methylphenidate (CONCERTA®) and generic novo-methylphenidate ER-C (NOVO-generic)

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Abstract

Objective:
Attention-deficit/hyperactivity disorder (ADHD) is a common neurobehavioral disorder with onset during childhood. Multiple aspects of a child's development are hindered, in both home and school settings, with negative impacts on social, emotional, and cognitive functioning. If left untreated, ADHD is commonly associated with poor academic achievement and low occupational status, as well as increased risk of substance abuse and delinquency. The objective of this study was to evaluate adult ADHD subject reported outcomes when switched from a stable dose of CONCERTA® to the same dose of generic Novo-methylphenidate ER-C®.

Methods:
Randomized, double-blind, cross-over, phase IV trial consisted of two phases in which participants with a primary diagnosis of ADHD were randomized in a 1:1 ratio to 3 weeks of treatment with CONCERTA or generic Novo-Methylphenidate ER-C. Following 3 weeks of treatment, participants were crossed-over to receive the other treatment for an additional 3 weeks. Primary efficacy was assessed through the use of the Treatment Satisfaction Questionnaire for Medication, Version II (TSQM-II).

Results:
Participants with ADHD treated with CONCERTA were more satisfied in terms of efficacy and side effects compared to those receiving an equivalent dose of generic Novo-Methylphenidate ER-C. All participants chose to continue with CONCERTA treatment at the conclusion of the study.

Conclusion:
Although CONCERTA and generic Novo-Methylphenidate ER-C have been deemed bioequivalent, however the present findings demonstrate clinically and statistically significant differences between generic and branded CONCERTA. Further investigation of these differences is warranted.