

ABSTRACT

A Double-Blind, Placebo-Controlled, Single Treatment, Dose-Finding, Safety, Tolerability and Preliminary Efficacy Study of BotB™ (Botulinum Toxin Type B) at Various Doses in Patients With Idiopathic Cervical Dystonia

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Intramuscular injection of botulinum toxin has become the treatment of choice for cervical dystonia (CD). This double-blind, placebo-controlled, multi-center study examined the safety, tolerability and efficacy of Botulinum Toxin Type B (BotB) in the treatment of patients with CD. Twelve centers enrolled and treated 122 patients who each received a single treatment of either placebo or BotB in doses of 2500 U, 5000 U, or 10,000 U. The primary measure of effectiveness was improvement from baseline to Week 4 in the Toronto Western Spasmodic Torticollis Rating Scale (TWSTRS) - Total score.

Improvement occurred at all dose levels and a clear dose-response was shown. In the analysis of covariance on TWSTRS-Total scores at Week 4, the overall difference among treatment groups was highly statistically significant ($P=0.0015$ for 2500 U; $P=0.0005$ for 5000 U; $P=0.0001$ for 10,000 U). The effectiveness of BotB was supported by the TWSTRS subscale scores for -Severity, -Pain, and -Disability and by Analog Pain Assessments and Investigator and Patient Global Assessments, which also indicated significantly greater effectiveness of BotB at higher doses. Treatment with BotB was safe and well tolerated. The frequency of adverse events for dry mouth and dysphagia appeared to be dose related. Most events considered related to treatment were mild or moderate in severity. This study indicates that BotB is safe and effective in significantly reducing the signs and symptoms of CD.

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