Botulinum Toxin A (BOTOX®) for Chronic Daily Headache: A Randomized, Placebo-Controlled, Parallel Design Study

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ABSTRACT

Introduction: Beneficial treatments for chronic daily headache (CDH) are limited. Botulinum toxin A (BHT) has been reported to help both migraine and tension headache. Methods: Study participants were randomized to receive either BTX or placebo injections. The study treatment period was 24 weeks, with a blinded period of 12 weeks and an open label period of 12 weeks. All patients were followed for 24 weeks. The primary outcome measure was the mean days per month with headache. Subsequent outcome measures included subjective and objective measures of headache relief, injection site adverse events, injection site complications, quality of life, and patient satisfaction. Results: Of the 60 subjects (49 female, mean age 47 ± 11 years), 34 were randomized to BTX, and 26 were randomized to placebo. The mean age of the 66 subjects (46 female) was 47.1 ± 11.1 years, and the mean days with headache were 23.7 ± 10.7 at BTO. A single 200 mg oral subset was included on a protocol violation for inactive BTZ and was excluded from the analysis. There was no difference between groups in terms of injection site adverse events or headache relief. Conclusion: In this study, BTX was well tolerated and significantly reduced headache days per month compared to placebo. Further research is needed to determine the long-term efficacy of BTX in CDH.

INTRODUCTION

Chronic daily headache (CDH) is a heterogeneous disorder, generally defined by greater than 15 headache days per month, which afflicts 2% of the population. 

Methods:

RESULTS

The mean age of the 60 subjects (49 female) was 47 ± 11.1 years, and the mean days with headache were 23.7 ± 10.7 at BTO. A single 200 mg oral subset was included on a protocol violation for inactive BTZ and was excluded from the analysis. There was no difference between groups in terms of injection site adverse events or headache relief. Conclusion: In this study, BTX was well tolerated and significantly reduced headache days per month compared to placebo. Further research is needed to determine the long-term efficacy of BTX in CDH.

REFERENCES