EFFICACY AND TOLERABILITY OF LONG-TERM XEOMIN® (BOTULINUM NEUROTOXIN TYPE A FREE FROM COMPLEXING PROTEINS) TREATMENT OF PATIENTS WITH BLEPHAROSPASM

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Aim: To assess the long-term efficacy and tolerability of XEOMIN® in a double-blind study with an open-label extension (OLEX) in blepharospasm.
Background: XEOMIN® has shown comparable efficacy and safety to Botox® (Allergan, USA) in blepharospasm when used in a 1:1 dosing.
Design/Methods: After completing a ≤20-week, placebo-controlled, double-blind main period (MP), and patients entered the OLEX period (≤69 weeks) and could receive ≤5 injection sessions (≤50 units XEOMIN®/eye/injection session). Outcome measures included: JRS sumscore, patient evaluation of global response, safety, and neutralizing antibody testing (mouse hemidiaphragm assay).
Results: JRS sumscore was significantly reduced during the MP ($p<0.001$). 102 patients entered the OLEX period with the following results. Mean total XEOMIN® doses were 64.7–72.7 units. At injection visits 1 to 5, mean JRS sumscores were: 5.9, 5.3, 5.0, 5.0, 4.9 points. Mean JRS sumscores were consistently and significantly reduced ($p<0.001$) 6 weeks after each injection: 3.4, 3.3, 3.1, 3.1, 3.4 points, respectively. Mean JRS sumscores significantly declined from 5.9 (1st injection visit) to 4.3 points (trial termination). A moderate or marked improvement or complete abolishment of symptoms was reported by ≥76% of patients, and investigators assessed tolerability as good or very good in ≥96% of patients during the 5 injection intervals. The AE profile was in line with findings from the MP. No patient had neutralizing antibodies at trial termination.
Conclusions/Relevance: XEOMIN® showed sustained efficacy and was well-tolerated in the treatment of blepharospasm for study duration of up to 89 weeks. Baseline symptoms of blepharospasm improved over the course of the study.