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Comparative Evaluation of the Safety and Efficacy of Botulinum Toxin Type A and Topical Creams for Treating Moderate-to-Severe Glabellar Rhytids

ABSTRACT

Several nonprescription products purport similar or better outcomes than botulinum toxin type A (Botox Cosmetic, Allergan Inc., Irvine, CA, USA) for treating wrinkles, but these have not been documented in comparative clinical trials. Patients spend millions of dollars annually on the topical products, yet there are, to date, no data to support any of the claims made.

To compare the efficacy and safety of botulinum toxin type A with placebo and three topical products in treating moderate-to-severe glabellar lines.

This single-center, randomized, investigator-blinded, parallel study of 77 female subjects comprised five treatment groups: botulinum toxin type A, placebo injection, StriVectin-SD (Klein-Becker USA, Salt Lake City, UT, USA), DDF Wrinkle Relax (Doctor's Dermatologic Formula, HDS Cosmetics, Inc., Yonkers, NY, USA), and HydroDerm (Hydroderm, Beverly Hills, CA, USA). Baseline and follow-up visits (weeks 4, 8, and 12) assessed safety and key efficacy measures: blinded investigator assessment of glabellar line severity on the Facial Wrinkle Scale (FWS), subjects' global assessment of overall change in appearance, subject ratings of glabellar-related self-perception pre- and post-treatment, and satisfaction with treatment.

Botulinum toxin type A treatment consistently resulted in statistically significant reductions in wrinkle severity on the FWS than any comparator ($p < .001$). Statistically significant improvements were similarly observed for subject-reported outcomes and satisfaction with botulinum toxin type A treatment, whereas treatment with any of the three topical creams did not result in a significant difference from placebo. Three adverse events occurred in three subjects who received StriVectin-SD.

Botulinum toxin type A provided significantly greater efficacy and patient satisfaction in the treatment of glabellar frown lines than StriVectin-SD, Wrinkle Relax, and HydroDerm, and in the objective measurements used, none of the topical preparations were better than botulinum toxin.

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