

## New type of botulinum toxin appears to be well tolerated and may help reduce forehead wrinkles

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Injections with a new type of botulinum toxin appears to be well tolerated and may help to improve the appearance of moderate to severe forehead lines with no evidence of diminishing treatment response over 13 months, according to a report in the March/April issue of *Archives of Facial Plastic Surgery*, one of the JAMA/Archives journals.

Injecting low doses of Clostridium botulinum toxin type A is a generally accepted method for treating lines on the face, according to background information in the article. A new botulinum toxin type A (Reloxin) has been used to treat neurological disorders outside the United States for more than 15 years and is approved to treat wrinkles in 23 countries. In the United States, this product has been under investigation for the treatment of glabellar or forehead lines since 2002, according to the authors.

Ronald Moy, M.D., of the Moy-Fincher Medical Group, Los Angeles, and colleagues report data from a phase 3, open-label study of 1,200 patients. Investigators injected 0.05 milliliters of solution, each containing 10 units of the new botulinum toxin, into each of five injection sites in the forehead at the beginning of each treatment cycle. Patients maintained diaries of treatment effects, were telephoned seven days later to check for adverse events and were re-examined clinically after two weeks, 30 days and again every month until their next treatment, withdrawal from the study or the end of the study. Based on



patient response, as many as five consecutive treatments were given with a minimum of 85 days in between.

A total of 1,052 patients completed the 13-month study. During the study period, 2,838 adverse events were experienced by 880 patients. Of those, 804 (28 percent) were considered probably or possibly related to the treatment, including events at the injection site (18 percent), nervous system disorders (14 percent) such as headache (12 percent) and eye events (9 percent, including 4 percent with ptosis, drooping of the eyelid or brow). Only one patient discontinued the study because of adverse events.

The authors suggest that based on investigators' and patients' assessments, the onset of effect and the duration of effect, the new botulinum toxin type A demonstrated benefits that did not diminish with repeat treatments. "The onset of effect was seen as soon as 24 hours and at a median [midpoint] of three days during all cycles," they write. By day seven of each treatment cycle, 93 percent to 95 percent of patients reported a response to treatment, and between 80 percent and 91 percent had a response by day 30 based on the investigators' assessments.

More information: Arch Facial Plast Surg. 2009;11[2]:77-83

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