Evaluation of the safety and efficacy of a biosimilar Abobotulinum toxin type A, in treating moderate to severe glabellar lines: A non-inferiority randomized control trial

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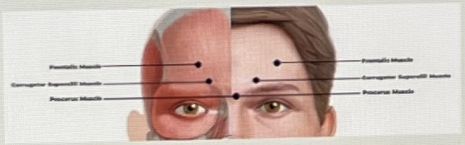
Introduction

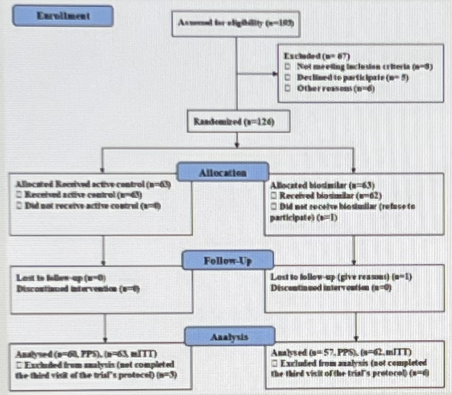
Injection of botulinum toxin type A for cosmetic purposes is a well-established practice.

This study was conducted to assess the efficacy and safety of an investigational biosimilar abo botulinum toxin type A (test product) compared to the standard abobotulinum toxin (active control) for improvement of moderate to severe glabellar lines.

Patients & Methods

This study was a double-blinded, randomized, controlled, non-inferiority, phase III clinical trial. Volunteers with moderate to severe glabellar lines according to Glabellar Line Severity Score (GLSS) were randomized in a 1:1 ratio to treatment with intramuscular injection of 40-60 units of either the test or control abobotulinum toxins type A . The response rate was defined as the percentage of volunteers with at least one grade improvement in GLSS at maximum frown and rest states 30 days after injection, which was assessed by 2 blind physicians. Secondary outcomes included the improvement of GLSS at maximum frown at 14, 60, 90 and 120 days after injection, as well as the side effects of the treatment.

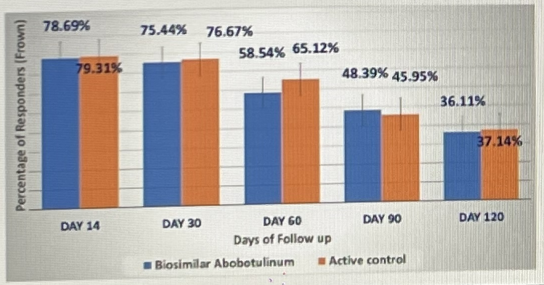




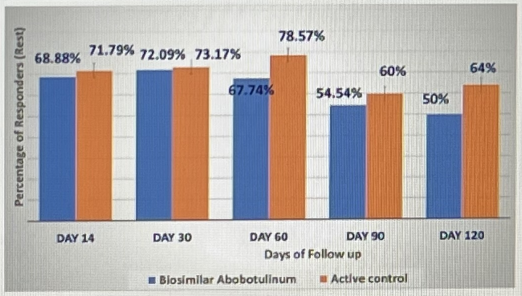
Results

To detect 15% non-inferiority margin for test product, 126 volunteers were enrolled in the study (62 and 63 volunteers in test and control groups respectively). No statistical difference was detected in age and baseline GLSS between two groups.

Thirty days after injection, the response rates were 75.44% (68.49-88.88) and 76.67% (69.30-89.31) at maximum frown state, and 87.7% and 88.89% at rest state, in the test and control groups (p values of 0.88 and 9.92), respectively.



Results



120 days after injection, the response rates were 36.11% (24.15-47.06) and 37.14% (25.20-49.07) at maximum frown state, in the test and control groups respectively (p values of 0.90). Adverse events were similar in both groups and mild, transient and well tolerated

Conclusion

Treatment of moderate to severe glabellar lines with biosimilar abobotulinum toxin type A was effective, tolerable, and non-inferior compared to the standard treatment in the 4-months follow up period.compared to the commercially available products.

References

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