

Meditoxin®, Proven Efficacy and Safety for Glabellar Frown Lines¹

PATIENTS

314 healthy adult patients (aged between 20 to 65) with moderate or severe glabellar lines at maximum frown.

* four- point scale (0=none, 1=mild, 2=moderate, 3=severe)

METHODS

Multicenter, double-blind, randomized, parallel design, active-controlled phase III clinical study. Each patient was randomly assigned to receive 20U (0.5ml) of either Meditoxin®(n=142) or Botox®(n=146). The total dose was distributed over 5 injection points into corrugators and procerus. Results of the treatment were evaluated at 4-week intervals: up to 16 week.

RESULTS

· **Efficacy:** Efficacy was evaluated based on glabellar lines improvement rate at maximum frown and the patient satisfaction.

1) Glabellar lines improvement rate at maximum frown:

There was no statistical difference between Meditoxin® and Botox®. This result demonstrated non-inferiority of Meditoxin® to Botox® in treatment of glabellar lines. (P>0.5) (Figure 1)

Improvement was defined as post-treatment glabellar lines severity score of 0(none) or 1(mild) from a baseline score of 2(moderate) or 3(severe), according to the investigator's live assessment of glabellar lines severity at maximum frown.

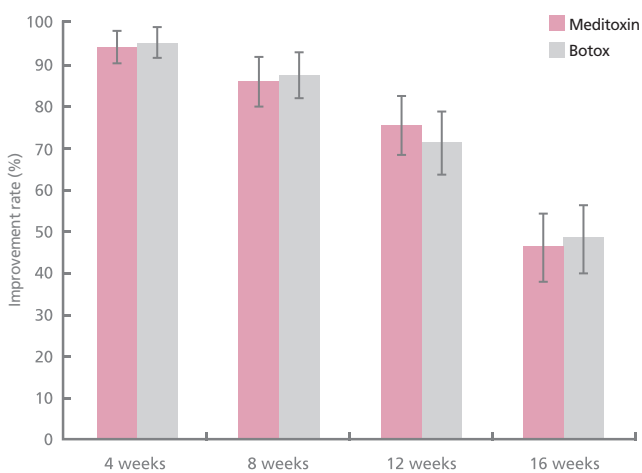


Figure 1. Glabellar lines improvement rate at maximum frown (PP set)

2) Patient satisfaction:

There was no statistical difference between Meditoxin® and Botox®. (P>0.5) (Figure 2)

The patient satisfaction score was quite high, about 6 based on a scale ranging from 1 (completely unsatisfied) to 7(completely satisfied).

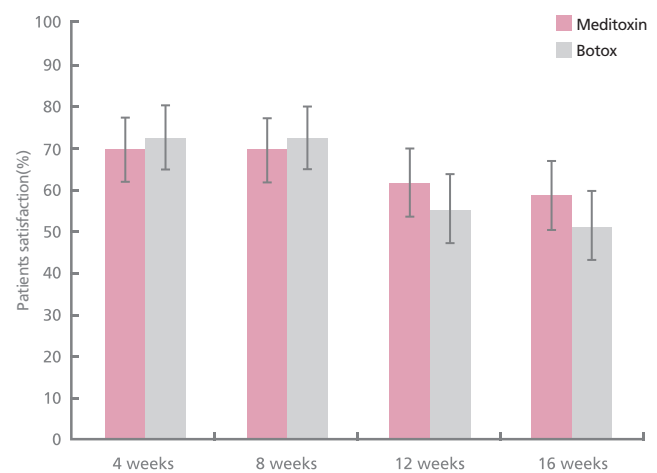


Figure 2. Patient satisfaction with the results (PP set)

· **Safety:** In this study, 26.92% of patients treated with Meditoxin® and 22.29% of patients received Botox® experienced adverse events. There was no statistical difference in the incidence and the severity of adverse events between two products (p=0.3416).

CONCLUSION

Meditoxin® was proved its non-inferiority to Botox®. Therefore, Meditoxin® is effective and safe for the treatment of glabellar frown lines.

*Meditoxin® is selling under different brand names as Neuronox, Siax, Cunox, and Botulift.