

Objectives: The primary objective was to evaluate the reduction of days with pain two months after one session of Botox/Placebo injection of the masseter and temporalis muscle

Methodology: The study was designed as a double-blind randomized controlled two-arm trial

Number of subjects (planned and analyzed): 48 planned; 46 analyzed

Diagnosis and main criteria for inclusion: Jaw muscle myalgia

Test product, dose and mode of administration: Botox, 100 Allergan units, intra-muscular injection in a total of 14 sites in the masseter and temporalis muscles

Duration of treatment: One session of treatment. Follow-up evaluation after 2 months

Reference therapy, dose and mode of administration: 0.9% sodium chloride Braun for parenteral injection (Braun, Melsungen, Germany) , intra-muscular injection in a total of 14 sites in the masseter and temporalis muscles

Criteria for evaluation: ITT analysis of all subjects subjected to treatment

Efficacy: The primary efficacy measure was the change from baseline in frequency of days with jaw functional pain at a 2-month follow-up

Safety: Adverse event registrations from time to treatment throughout the 2-month follow-up period. Subject reported as well as observed by investigator staff

Statistical methods: Primary efficacy variable was analyzed with the Mann-Whitney U-test.

Summary – Conclusions: Efficacy Results: Between baseline and the 2 month follow-up the primary efficacy variable change in number of pain days decreased from a median of 14.0 ($q_1; q_3$ 10.0;14.0) to 10.5 ($q_1; q_3$ 4.0;14.0) ($p=.018$) in the Botox group and from 14.0 ($q_1; q_3$ 12.5;14.0) to 14.0 ($q_1; q_3$ (9.0;14.0) ($p=.168$) in the Placebo group. There was no statistically significant difference between the groups ($p=.676$).

Safety Results: Adverse reactions were mild and transient in both groups.

Conclusion: The study showed a numerically greater reduction in number of pain days in the Botox group compared to Placebo. However, the difference was statistically non-significant probably because of low power.