SAFETY AND EFFICACY OF ONABOTULINUMTOXINA FOR TREATMENT OF MASSETER MUSCLE HYPERTROPHY: RESULTS FROM A PHASE 2 DOSE-ESCALATION STUDY

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Eligibility Criteria
• Participants were aesthetically oriented, aged 18-50 years, with a history of bilateral masseter hypertrophy (MMH). MMH was defined as measured at screening and confirmed on day 1 by the investigator using a 5-grade Masseter Muscle Prominence Scale (MPS) (P<0.001) (Table 1).

• MMH may impact an individual's self-perception of facial attractiveness and health-related quality of life. Additionally, studies have associated increased risk of facial pain and jaw movement (2). Treatment options for MMH range from pharmacotherapy to surgical reduction (3).

• This multicenter, randomized, double-blind, placebo-controlled, phase 2 dose-escalation study assessed the safety and efficacy of onabotulinumtoxinA (onabotA) 24 U or placebo in participants with MMH.

METHODS

RESULTS

SUMMARY

Table 1. Baseline Clinical Characteristics

Table 2. Summary of Adverse Events

DISCLOSURES

REFERENCES

CONCLUSIONS

1. The only discontinuation attributable to AEs occurred in the placebo group.
2. No safety trends or patterns identified with a dose increase were observed; however, facial paresis (weakness when smiling, altered smile, right depressor labia inferioris paresis) and subject-reported possible loss of movement along jawline was only reported in the highest (96 U) onabotA dose group.
3. No reported AEs indicated a distant spread of toxin.

BACKGROUND

The data used in this analyses are associated with specific institutions, including jaw pain.

TREATMENT OPTIONS FOR MMH RANGE FROM PHARMACOTHERAPY TO SURGICAL REDUCTION.

WELL-CONTROLLED CLINICAL TRIALS ARE NEEDED TO DOCUMENT THE SAFETY AND EFFICACY OF ONABOTULINUMTOXINA IN THE TREATMENT OF MMH.

REFERENCES