Efficacy of Kinetic Oscillation Stimulation for the preventive treatment of chronic migraine

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Introduction

- The trigemino-autonomic reflex and parasympathetic outflow play a significant role in migraine pathophysiology[1].
- Parasympathetic neuropeptides such as PACAP and VIP can trigger migraine attacks suggesting along with preclinical data that modulating parasympathetic outflow may provide an effective treatment target[2,3,4].
- Kinetic Oscillation Stimulation (K.O.S) with the Chordate system in the nasal cavity provides a robust activation of the parasympathetic outflow causing cranial autonomic symptoms such as lacrimation[5].

Aim

To investigate the clinical efficacy of K.O.S for the preventive treatment of chronic migraine.

Methods

- Data represents the results of a multicentre, randomised, sham-controlled clinical trial (PM007, NCT03400059).
- K.O.S stimulation (85Hz, 80 mbar) or sham stimulation (0Hz, 30 mbar) were conducted for 10 min per nostril 1x per week over a period of 6 weeks.
- **Primary endpoint**: Mean change from baseline in monthly headache days (MHD) with moderate to severe intensity in 4-week performance assessment period.
- Secondary endpoints included the mean change from baseline in MHD with moderate to severe intensity in 4-week follow-up period, the change in monthly migraine days in assessment and follow-up periods, and the 30% responder rate.

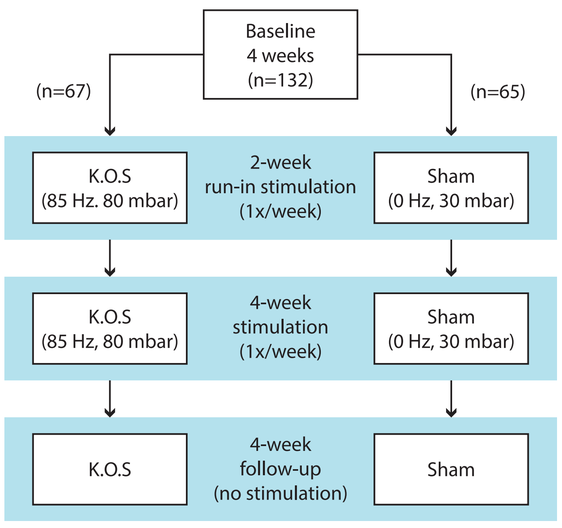

Figure 1: Study design

A

B

Figure 2: (A) K.O.S controlling unit (Chordate S211), (B) Nasal stimulation catheter.

Conclusions

- The trial shows that K.O.S is an effective and safe option for the preventive treatment of chronic migraine.
- K.O.S offers a valuable non-pharmacologic treatment option with a more favourable side effect profile compared to systemic treatments.

Results

1. K.O.S significantly reduced the number of MHD with moderate to severe intensity from baseline when compared to sham stimulation (Figs. 3A, 3B).

2. The effect was sustained during the 4-week post-treatment follow-up period (Figs. 3A, 3B).

3. K.O.S sigificantly reduced the number of monthly migraine days from baseline when compared to sham stimulation (Figs. 4A, 4B).

4. A ≥30% reduction in MHD with moderate to severe intensity from baseline was achieved in 47.1% of patients using K.O.S vs. 25.4% using sham (Fig. 5).

5. No serious adverse events occurred during the study.

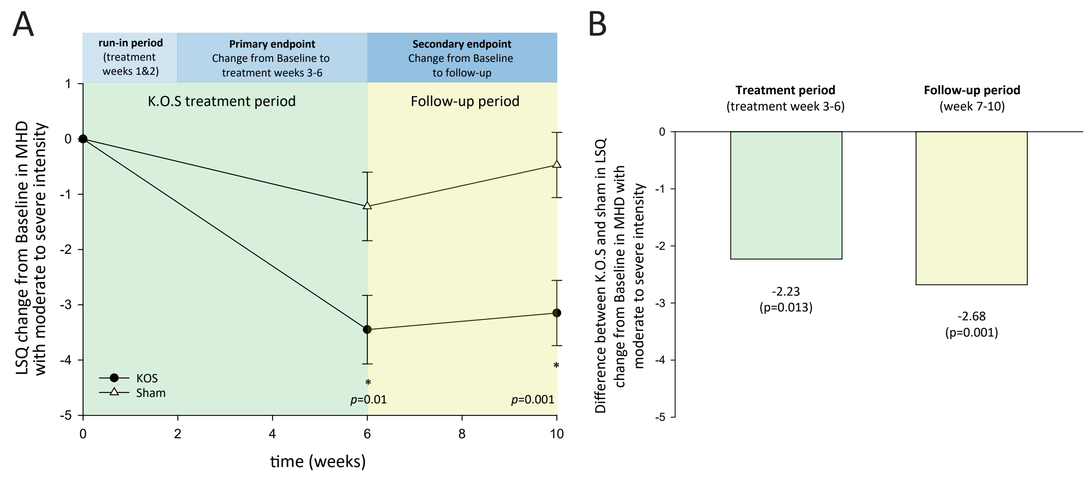

Figure 3: Fig. 3A shows the least square means (LSQ) change in **headache days with moderate to severe intensity (MHD)** from baseline to treatment weeks 3-6 and follow-up period. Fig. 3B depicts therapeutic gain.

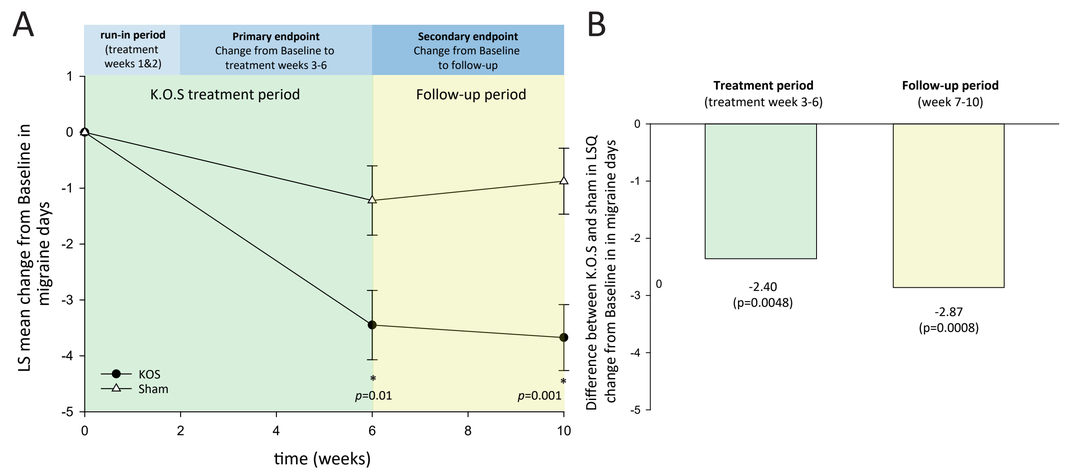

Figure 4: Fig. 4A shows the LSQ change in **migraine days** from baseline. Fig. 4B depicts the therapeutic gain.

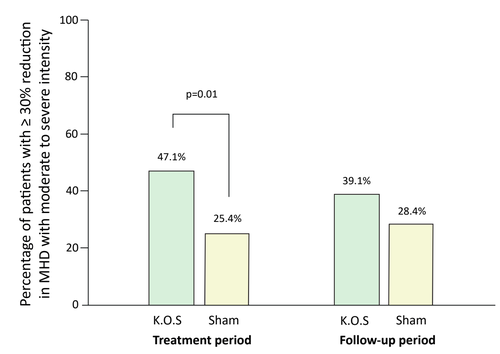

Figure 5: 30% responder rate of MHD reduction.

References

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