Kinetic Oscillation Stimulation for the treatment of chronic migraine - a subgroup analysis of a randomised controlled clinical trial

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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 Chordate S211 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 subgroup analysis on the German study population (n=92) of a larger 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.

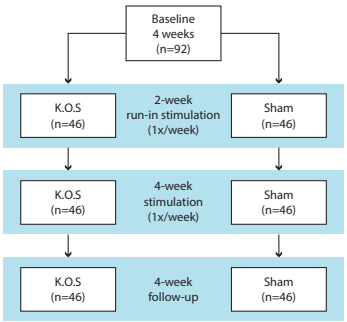

Figure 1: Study design

A B

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

Conclusions

- The subgroup analysis shows that K.O.S is an effective and safe option for the preventive treatment of chronic migraine.
- K.O.S will be 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 (Fig. 3, 4A).

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

3. A ≥30% reduction in MHD with moderate to severe intensity from baseline was achieved in 41.4% using K.O.S vs. 14.9% in sham (Fig. 4B).

4. No serious adverse events occurred during the study.

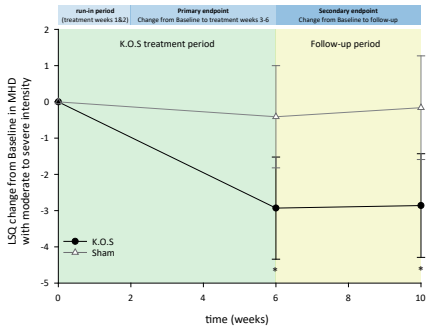

Figure 3: Least square means (LSQ) of change from baseline to treatment weeks 3-6 and follow-up period.

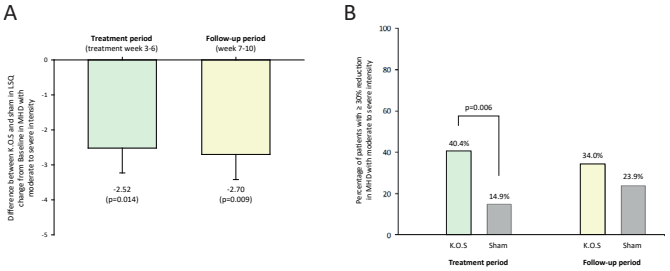

Figure 4: Figures 3 and 4A show a difference for LSQ of the ANCOVA model, containing terms for treatment, baseline value, and medication overuse headache between the 4-week baseline period and treatment weeks 3-6 of -2.52 (CI95%=[-4.52; -0.52], p=0.014; using non-parametric, stratified van Elteren test p=0.009); Figure 4B 30% response rate (Chi-Square test).

References

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