Safety and Efficacy of Cervical 10 kHz Spinal Cord Stimulation (SCS) for the Management of Refractory Chronic Migraine*: A Prospective Study

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Introduction

• Significant unmet need: effective therapies for refractory Chronic Migraine (CM)
• Neurostimulation therapies (i.e. occipital nerve stimulation) showed disappointing therapeutic effects in large clinical trials1.
• Recent prospective study: HF-SCS shown promising efficacy in refractory CM and medication overuse subjects2.

Study design & goal

• Single-center, open label, prospective, feasibility (of label) study
• Follow-up 12 months
• Safety, tolerability and efficacy of HF-SCS in refractory Chronic Migraine subjects

Methods

• Treatment of Chronic Migraine is investigational only and not on-label or indicated for use
• Age: ≥18 years old
• Chronic migraine with/without aura
• Refractory to ≥ 3 preventive treatments: ✓ Topiramate & Botox (< 30% pain relief)

Exclusion

• Medication overuse headache
• Severe depression (PhQ-9>19)

Implant Procedure

• Spinal Cord Stimulator (HF10)
  (Senza System, Nevro Corp, Redwood City, CA)
• Leads positioned at C2
• No stimulation trial
• Responder = at least 30% reduction in headache days per month post-device activation

Results

Excluded due to:
• Subject withdrawn consent (n=2)
• MRI showed narrow spinal canal (n=1)
• PHQ score above cutoff (n=1)

Results (contd.)

Anticipated Device related Adverse Effects:
• 5 subjects reported mild to moderate IPG pain
• 1 subject experienced slight lead movement
• No explants

Conclusions

• HF-SCS may offer a safe & effective therapeutic option for refractory Chronic Migraine
• Efficacy similar as for Occipital Nerve Stimulation (ONS), however subjects treated with HF-SCS significantly more refractory
• Lack of implant-related additional surgery suggests that HF-SCS may offer a safer profile than ONS

Disclosure

This study was sponsored by Nevro.

References

1. Dodick DW et al, Cephalalgia, 2015