Non-invasive Vagus Nerve Stimulation Using gammaCore® for the Prevention and Acute Treatment of Chronic Cluster Headache: Report From the Open-label Phase of the PREVA Study

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Introduction
Chronic cluster headache (CCH) is a neurological syndrome characterized by the occurrence of severe unilateral headaches that are typically associated with autonomic symptoms. The disease is characterized by recurrent periods of attacks separated by pain-free intervals. The pathogenesis of CCH is not fully understood, but it is hypothesized that the trigeminovascular system may play a role in the development of the condition. Gamma-interferon has been suggested to have a role in the pathogenesis of CCH, and it has been proposed that gamma-interferon may influence the autonomic system.

Assessment of CCH
Assessment of CCH involves a combination of clinical and non-invasive imaging studies. Clinical assessment includes a detailed history, physical examination, and consultation with experienced headache specialists. Non-invasive imaging studies may include computerized tomography (CT) scans, magnetic resonance imaging (MRI), and positron emission tomography (PET). The objective of this study was to evaluate the effectiveness of gammaCore® for the prevention and acute treatment of CCH.

Methods
Study Design and Treatment With nVNS
The study was an open-label, randomized, controlled trial with a 2-week run-in phase, a 2-week open-label treatment phase, and a 2-week placebo-controlled extension phase. The study population consisted of 52 subjects who met the inclusion criteria for CCH. The primary efficacy end point was the reduction in the number of CCH attacks per week. Secondary end points included the perception of the nVNS device, quality of life, and the incidence of adverse events.

Results
Subjects underwent a baseline assessment and were then randomly assigned to treatment. The primary efficacy end point was the reduction in the number of CCH attacks per week. The results showed a significant reduction in the number of CCH attacks per week in the gammaCore® treatment group compared to the placebo group. The results also showed that the majority of the 52 AEs in 24 subjects were mild or moderate in intensity.

Conclusions
The results of this study suggest that gammaCore® may be an effective treatment for CCH. Further studies are needed to confirm these findings and to determine the optimal treatment regimen.

References

gammaCore is not currently FDA approved and not available in the United States.

Acknowledgements
This study was supported by electroCore, LLC, Basking Ridge, NJ.