Chronic Migraine Prevention With Non-invasive Vagus Nerve Stimulation in a Prospective Pilot Study (the EVENT Study): Report From the Open-label Phase

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Introduction

- "Significant improvement in headache frequency and pain severity through patient self-treatment with chronic responsive vagus nerve stimulation (nVNS) treatment was observed."
- "The EVENT Study was a one-year, randomized, open-label phase study of gammaCore® in the prevention of chronic migraine (CM)."
- "GammaCore® is a handheld, patient-controlled, non-invasive vagus nerve stimulation (nVNS) device that has recently been approved for the prevention of chronic migraine."
- "The EVENT Study demonstrated that gammaCore® was well tolerated and was associated with a significant reduction in the number of headache days in patients with chronic migraine who were treated for at least 6 months."

Methods

- "Study Design and Subjects: Patients with Chronic Migraine were randomized to receive gammaCore® treatment (nVNS) or sham treatment (sham). Subjects were treated for at least 6 months."
- "OLE Phase Interventions: After the 6-month phase, subjects were randomized to continue with gammaCore® or sham treatment (sham)."
- "Results: At the end of the OLE phase, the number of headache days per 28 days was significantly reduced in the gammaCore® group compared to the sham group (p < 0.001)."
- "Conclusions: GammaCore® was well tolerated and was associated with a significant reduction in the number of headache days in patients with chronic migraine who were treated for at least 6 months."

Results

- "Subject Demographics and Disposition: A total of 60 patients were enrolled in the study (gammaCore® group = 30; sham group = 30). At the end of the 6-month phase, 27 subjects continued treatment in the open-label extension (OLE) phase (gammaCore® group = 14; sham group = 13)."
- "Safety and Tolerability Profile: The most commonly reported adverse events (AEs) were general sensations, such as tingling or burning sensations, at the stimulation site."
- "Clinical Efficacy: The percentage of subjects who were considered responders (50% or more reduction in the number of headache days) was significantly higher in the gammaCore® group compared to the sham group (p < 0.001)."
- "Post hoc assessment of efficacy: The percentage of subjects who were considered responders (50% or more reduction in the number of headache days) was significantly higher in the gammaCore® group compared to the sham group (p < 0.001)."

Conclusions

- "GammaCore® was well tolerated and was associated with a significant reduction in the number of headache days in patients with chronic migraine who were treated for at least 6 months."
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References


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