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MEETING ABSTRACT Open Access

EHMTI-0363. Quality of life in subjects treated by non-invasive vagus nerve stimulation using gammacore® for the prevention and acute treatment of chronic cluster headache

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Introduction

The debilitating nature of chronic cluster headache (CH) can negatively impact a patient's quality of life (QoL). In recent years, non-invasive neuromodulation devices have been of increasing interest for the treatment of CH.

Aim

The Prevention and Acute Treatment of Chronic Cluster Headache (PREVA) study was designed to evaluate the clinical effects—including QoL outcomes—of gammaCore®, a non-invasive vagus nerve stimulation device (nVNS), in subjects with chronic CH.

Methods

PREVA was a randomized, well-controlled study comprised of a 2-week run-in phase, a 4-week randomized (1:1; nVNS vs standard of care [SoC]) phase, and a 4-week extension phase. Subjects delivered stimulations prophylactically twice daily (mandatory) or optionally for the rescue treatment of CH attacks. Three validated scales (EQ-5D-3L™, Headache Impact Test™ [HIT-6], and Hospital Anxiety and Depression Scale [HADS]) were used to assess the QoL of subjects at the end of each study phase.

Results

A total of 97 subjects were randomized to treatment; data from 93 subjects (n = 45 nVNS; n = 48 SoC) were included in the efficacy analysis population. Compared with subjects treated with SoC alone, subjects also treated with nVNS reported greater overall improvements in EQ-5D-3L, HIT-6, and HADS scores from the end of run-in to the end of the randomized phase. As of June 2014, QoL data from the extension phase were not available; however, they will be available for presentation at EHMTIC.

Conclusion

Compared with SoC, use of nVNS for the both preventive and acute treatment of CH was associated with greater improvement in QoL as assessed on 3 validated instruments.

Abstract submitted on behalf of the PREVA Study Investigators.

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