

MEETING ABSTRACT

Open Access

EHMTI-0364. Non-invasive vagus nerve stimulation using gammaCore[®] for prevention and acute treatment of chronic cluster headache: report from the randomized phase of the PREVA study

C Gaul^{1*}, H Diener², K Solbach², N Silver³, A Straube⁴, D Magis⁵, U Reuter⁶, A Andersson⁷, EJ Liebler⁸

From 4th European Headache and Migraine Trust International Congress: EHMTIC 2014 Copenhagen, Denmark. 18-21 September 2014

Introduction

Cluster headache (CH) is a painful and debilitating disorder for which non-invasive vagus nerve stimulation (nVNS) may be a treatment option.

Aim

Compare the efficacy of gammaCore[®], a handheld nVNS device, with the standard of care (SoC) in chronic CH subjects in the randomized phase of the Prevention and Acute (PREVA) Treatment of Chronic Cluster Headache study.

Methods

PREVA was a multicenter study comprised of 3 phases: 2-week run-in, 4-week randomized (1:1; nVNS vs SoC), and 4-week extension. Subjects randomized to nVNS delivered stimulations prophylactically twice daily (mandatory) and optionally for the rescue treatment of CH attack. The primary efficacy end point was the reduction in number of CH attacks/week during the last 2 weeks of the randomized phase versus the run-in phase. Additional end points included the proportion of subjects with > 50% reduction in CH attacks/week (response rate) and rescue medication use; safety was assessed by monitoring the frequency of adverse events.

Results

Ninety-seven subjects were randomized; data from 93 subjects (n = 45 nVNS; n = 48 SoC) were included in the intention-to-treat population. Number of CH attacks/week was significantly reduced in subjects treated with nVNS compared with patients treated with SoC only (-7.6 vs -2.0; P = .002). Further, significantly more nVNS- than SoC-treated subjects were considered treatment responders (34.4% vs 7.1%; P = .003). nVNS was associated with less use of rescue medications and demonstrated a favorable safety/tolerability profile.

Conclusion

Prophylactic treatment of chronic CH with nVNS is safe and, compared with SoC, reduces frequency of CH attacks/week. Sham-controlled studies are warranted and underway to confirm these data.

Abstract submitted on behalf of the PREVA Study Investigators.

Authors' details

¹Migraine and Headache Clinic, University of Duisburg-Essen, Königstein, Germany. ²Department of Neurology, University Hospital Essen, Essen, Germany. ³Department of Neurology, Walton Centre for Neurology and Neurosurgery, Liverpool, UK. ⁴Department of Neurology, Ludwig Maximilian University of Munich, Munich, Germany. ⁵Department of Neurology, Liège University, Liège, Belgium. ⁶Berlin NeuroImaging Center, Charité University Hospital, Berlin, Germany. ⁷Clinical Affairs, electroCore Medical, Gothenburg, Sweden. ⁸Scientific Medical and Clinical Affairs, electroCore LLC, Basking Ridge, USA.

¹Migraine and Headache Clinic, University of Duisburg-Essen, Königstein, Germany

Full list of author information is available at the end of the article

Published: 18 September 2014

doi:10.1186/1129-2377-15-S1-17

Cite this article as: Gaul et al.: EHMTI-0364. Non-invasive vagus nerve stimulation using gammacore[®] for prevention and acute treatment of chronic cluster headache: report from the randomized phase of the preva study. *The Journal of Headache and Pain* 2014 **15**(Suppl 1):17.

Submit your manuscript to a SpringerOpen[®] journal and benefit from:

- ▶ Convenient online submission
- ▶ Rigorous peer review
- ▶ Immediate publication on acceptance
- ▶ Open access: articles freely available online
- ▶ High visibility within the field
- ▶ Retaining the copyright to your article

Submit your next manuscript at ▶ springeropen.com
