

Vagus nerve stimulation for cluster headache

Results from a prospective, randomised, open-label [PREVA study](#) suggested that adjunctive treatment with a novel non-invasive [vagus nerve stimulation](#) (nVNS) device led to decreased attack frequency and abortive medication use in patients with chronic [cluster headache](#) (cCH).

In all scenarios modelled from a German perspective, nVNS was cost-effective compared with current standard of care (SoC), which suggests that adjunctive nVNS therapy provides economic benefits in the treatment of cCH. Notably, the current analysis included only costs associated with abortive treatments. Treatment with nVNS will likely promote further economic benefit when other potential sources of cost savings (e.g. reduced frequency of clinic visits) are considered ¹⁾.

A study compared nVNS with a sham device for acute treatment in patients with episodic or chronic CH (eCH, cCH). **Methods** After completing a 1-week run-in period, subjects were randomly assigned (1:1) to receive nVNS or sham therapy during a 2-week double-blind period. The primary efficacy endpoint was the proportion of all treated attacks that achieved pain-free status within 15 minutes after treatment initiation, without rescue treatment. **Results** The Full Analysis Set comprised 48 nVNS-treated (14 eCH, 34 cCH) and 44 sham-treated (13 eCH, 31 cCH) subjects. For the primary endpoint, nVNS (14%) and sham (12%) treatments were not significantly different for the total cohort. In the eCH subgroup, nVNS (48%) was superior to sham (6%; $p < 0.01$). No significant differences between nVNS (5%) and sham (13%) were seen in the cCH subgroup. **Conclusions** Combining both eCH and cCH patients, nVNS was no different to sham. For the treatment of CH attacks, nVNS was superior to sham therapy in eCH but not in cCH. These results confirm and extend previous findings regarding the efficacy, safety, and tolerability of nVNS for the acute treatment of eCH ²⁾.

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Morris J, Straube A, Diener HC, Ahmed F, Silver N, Walker S, Liebler E, Gaul C. Cost-effectiveness analysis of non-invasive vagus nerve stimulation for the treatment of chronic cluster headache. *J Headache Pain*. 2016 Dec;17(1):43. doi: 10.1186/s10194-016-0633-x. Epub 2016 Apr 22. PubMed PMID: 27102120.

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Goadsby PJ, de Coo IF, Silver N, Tyagi A, Ahmed F, Gaul C, Jensen RH, Diener HC, Solbach K, Straube A, Liebler E, Marin JC, Ferrari MD; ACT2 Study Group. Non-invasive vagus nerve stimulation for the acute treatment of episodic and chronic cluster headache: A randomized, double-blind, sham-controlled ACT2 study. *Cephalalgia*. 2017 Jan 1:333102417744362. doi: 10.1177/0333102417744362. [Epub ahead of print] PubMed PMID: 29231763.

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