PREVA was a prospective, open-label, randomised study that compared adjunctive prophylactic nVNS (n = 48) with standard of care (SoC) alone (control (n = 49)). A two-week baseline phase was followed by a four-week randomised phase (SoC plus nVNS vs control) and a four-week extension phase (SoC plus nVNS). The primary end point was the reduction in the mean number of CH attacks per week. Response rate, abortive medication use and safety/tolerability were also assessed.

During the randomised phase, individuals in the intent-to-treat population treated with SoC plus nVNS (n = 45) had a significantly greater reduction in the number of attacks per week vs controls (n = 48) (-5.9 vs -2.1, respectively) for a mean therapeutic gain of 3.9 fewer attacks per week (95% CI: 0.5, 7.2; p = 0.02). Higher ≥50% response rates were also observed with SoC plus nVNS (40% (18/45)) vs controls (8.3% (4/48); p < 0.001). No serious treatment-related adverse events occurred.

Adjunctive prophylactic nVNS is a well-tolerated novel treatment for chronic CH, offering clinical benefits beyond those with SoC [1].

1)
Gaul C, Diener HC, Silver N, Magis D, Reuter U, Andersson A, Liebler EJ, Straube A; PREVA Study Group. Non-invasive vagus nerve stimulation for PREVention and Acute treatment of chronic cluster headache (PREVA): A randomised controlled study. Cephalalgia. 2016 May;36(6):534-46. doi: 10.1177/0333102415607070. Epub 2015 Sep 21. PubMed PMID: 26391457.