

EHMTC-0154
POSTER SESSION D

EFFECTS OF NON-INVASIVE VAGUS NERVE STIMULATION ON ATTACK FREQUENCY OVER TIME AND RESPONSE RATES IN PATIENTS WITH CHRONIC CLUSTER HEADACHE

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Background: In the PREVA study of chronic cluster headache (cCH) prophylaxis, attack frequency reductions from baseline were significantly more pronounced with non-invasive vagus nerve stimulation (gammaCore[®]) plus standard of care (nVNS + SoC) than with SoC alone.

Aim: To evaluate the time to and magnitude of nVNS benefits in PREVA ad hoc analyses.

Methods: Subjects received SoC during the 2-week baseline period followed by nVNS + SoC or SoC alone during

the 4-week randomised phase (RP). In the optional 4-week extension phase (EP), all subjects received nVNS + SoC. The nVNS treatment comprised three 2-minute stimulations administered twice daily (6 stimulations total per day).

Results: Mean weekly attack frequency was significantly lower with nVNS + SoC than with SoC alone from RP week 2 through EP week 3; this difference diminished by EP week 4 (Figure). For the nVNS + SoC group, attack frequency was significantly lower at RP week 1 through EP week 4 than at baseline and was relatively stable during the EP. Response rates were significantly greater with nVNS + SoC than with SoC alone when response was defined as attack frequency reductions of $\geq 25\%$, $\geq 50\%$, and $\geq 75\%$ from baseline ($P \leq 0.01$).

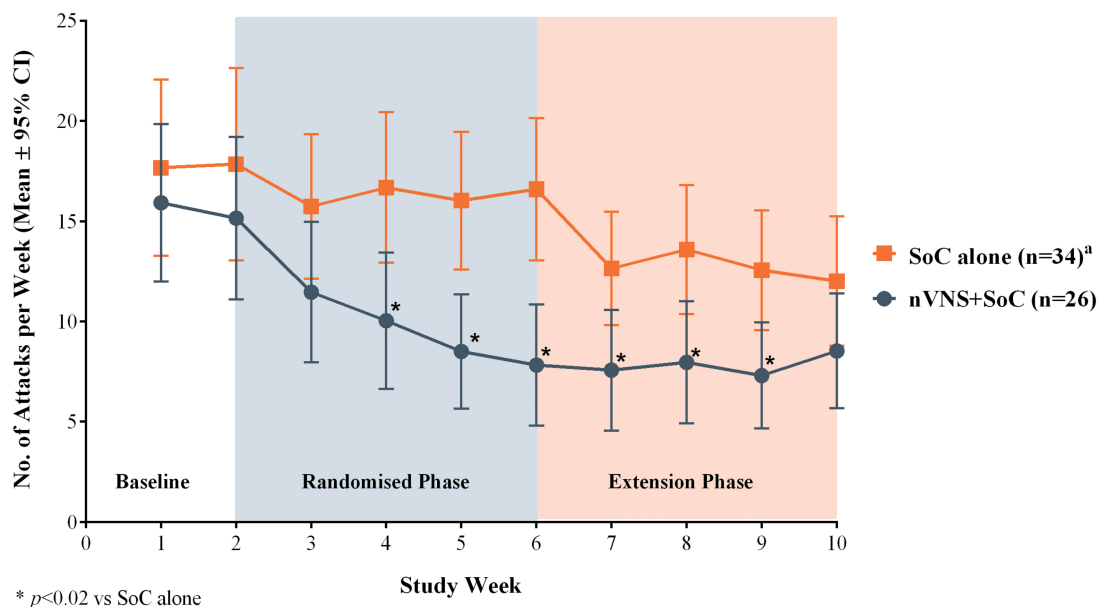
Conclusions: Prophylactic nVNS led to rapid, significant, and sustained reductions in cCH attack frequency as early as 2 weeks after addition to SoC and was associated with significantly higher $\geq 25\%$, $\geq 50\%$, and $\geq 75\%$ response rates vs SoC alone.

Conflict of interest

Disclosure statement:

Dr. Charly Gaul, MD, has received honoraria from Allergan plc, Autonomic Technologies, Inc., Bayer AG, Boehringer Ingelheim GmbH, Desitin Arzneimittel GmbH, electroCore, LLC, Grünenthal GmbH, Hormosan

Figure: Mean Attack Frequencies (mITT Population)



Abbreviation: mITT, modified intent-to-treat.

^a Subjects received SoC alone in the RP and nVNS+SoC in the EP.

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