2023. Vagus nerve

RCT/CD/ Induction

Neuroimmune modulation through vagus nerve stimulation reduces inflammatory activity in Crohn's disease patients: a prospective open label study

Multicenter, open-label clinical trial.

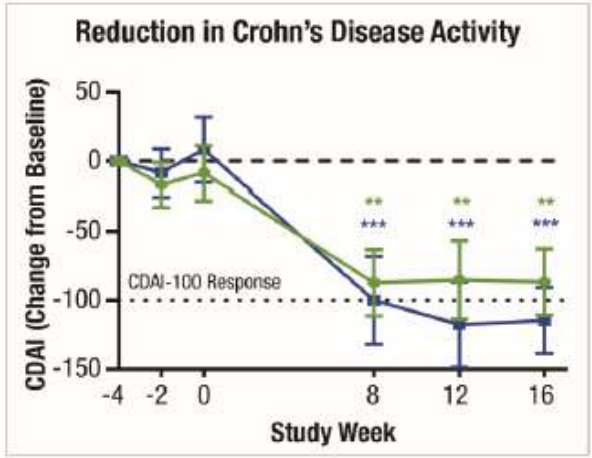
Patients with Crohn's disease moderately-severely active who were treatment-refractory were implanted a vagus nerve stimulator (VNS) for 16 weeks.
*AZA, MCP and MTX could be continued. After a protocol modification biologics (antiTNF and vedolizumab) were allowed if stable dose for >6 months

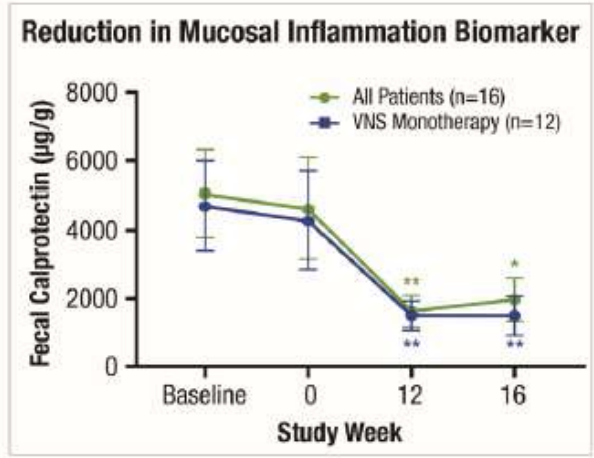
Primary endpoints: Mean change in CDAI between preimplantation and week 16.

Results: N=16
(4 of the patients were on biologics, the rest 12 were on VNS monotherapy)

- There was a significant and clinically meaningful decrease in CDAI (p=0.003), fecal calprotectin (p=0.015), decrease
- There was one study-related SAE: a post-operative infection requiring device explantation.

Conclusion:
Neuroimmune modulation via vagus nerve stimulation was generally safe and well-tolerated with a clinically meaningful reduction in clinical disease activity associated with endoscopic improvement, reduced levels of faecal calprotectin and serum cytokines, and improved quality-of-life.





D'Haens G et al. J Crohns Colitis. 2023;