

TITLE: Electrical Neuromodulation and the Treatment of Primary Headache

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Neuromodulation is a therapeutic alteration of nervous system activity by means of a device, either electrical or pharmacological. In the past, the most commonly employed neuromodulation devices have required invasive procedures. For example, vagus nerve stimulation (VNS) has required surgical implantation in the neck; the morbidity associated with this procedure, coupled with the cost of the device; have limited the potential for frequent use.¹

Due to a recent shift towards developing less invasive stimulation methods, the field of neuromodulation is experiencing tremendous growth and a number of new devices have emerged.²³⁴⁵⁶ Although some evidence for their efficacy is currently available, randomized, placebo or sham-controlled data, assessing the therapeutic potential of these neuromodulation devices, is very limited. This makes it difficult for clinicians to integrate these techniques into their treatment paradigm.

A novel neurostimulation technology (utilizing the gammaCore[®] device) for primary headache disorders, consists of a proprietary electrode configuration and signal that allows vagal nerve stimulation (nVNS) to be delivered to the cervical branch of the vagus nerve transcutaneously in a non-invasive approach. The device is portable and offers the possibility to control the stimulation, which lasts 90 seconds per treatment.

GammaCore therapy has been initially studied in a number of open-label clinical trials.⁷ One cluster headache study reported 13 of the 14 patients having a mean estimated subjective improvement of 60% from baseline.⁸ The treatment will be studied in multiple randomized clinical studies in 2013, examining its safety and efficacy. It will be evaluated both for migraine and cluster headache, both as a preventive and acute treatment. The combined expected enrollment in the United States and Europe will exceed 400 patients. Should the data from these studies be as positive as the early open-label results, this will represent an important and exciting new treatment option.

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