FDA OKs vagus nerve stimulator to treat cluster headaches

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(HealthDay)—A new noninvasive device, gammaCore, which works to

reduce cluster headache pain by transmitting mild electrical stimulation to the vagus nerve through the skin on the neck, has been approved by the U.S. Food and Drug Administration.

The gammaCore technology is made by the U.S.-based neuroscience and technology company electroCore. The FDA approval of gammaCore was based on two clinical trials that found the device was more effective than placebo in reducing cluster headache pain.

One trial of 85 patients with episodic cluster headache found that the device reduced pain in 34.2 percent of patients compared to 10.6 percent of those on placebo. A second trial of 27 patients found that pain had ceased by 15 minutes after headache onset for a higher percentage of participants using the device compared to those on placebo (47.5 versus 6.2 percent). According to a company news release, "gammaCore was found to be safe and well tolerated," with most side effects being "mild and transient."

The device should not be used by patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device; those diagnosed with carotid atherosclerosis; those who have had cervical vagotomy; individuals with clinically significant hypertension, hypotension, bradycardia, or tachycardia; and children or pregnant women. It should also not be used by patients with a metallic device such as a stent, bone plate, or bone screw implanted in or near the neck, or patients who are using another medical device at the same time or any portable electronic device (for example, a mobile phone).

More information: More Information