

Best Headache Devices Available in the USA 2022

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Background: Non-interventional medical devices cleared by the FDA in the USA now allow physicians to offer relief to patients who do not want medication or cannot tolerate them. Devices can also be used along with medication. They work either on various types of electrical neuromodulation to nerves outside the brain or magnetic stimulation to the back of the brain itself to reach pain-associated pathways. A 2019 report on pain management from the US Department of Health and Human Services noted that some RCTs and other studies “have demonstrated that non-invasive vagal nerve stimulation can be effective in ameliorating pain in various types of cluster headaches and migraines.”

At least three devices, one designed to stimulate both the occipital and trigeminal nerves (eCOT-NS, Relivion, Neuro Relief Ltd), one that stimulates the vagus nerve, (nVNS, gammaCORE, electroCore) and one that stimulates peripheral nerves in the upper arm REN, Nerivio, Theranica Bio-Electronics LTD are FDA-cleared to treat episodic and chronic migraine; nVNS is also cleared to treat migraine, episodic cluster headache acutely and chronic cluster acutely in conjunction with medication.

The devices

NERIVIO

Theranica Bio-Electronics LTD, makes a remote electrical neuromodulation device (REN) called Nerivio, which is FDA-cleared to treat migraine acutely in adults and adolescents. Recent studies have shown effectiveness in migraine prevention and treating menstrual migraine. The patient wears the device on her upper arm where sensory fibers, once stimulated in the arm, travel up to the brainstem to affect the serotonin-modulated descending inhibitory pathway to disrupt incoming pain messaging. Theranica has applied to the FDA for clearance to treat patients with chronic migraine and soon prevention of migraine.

RELIVION

Neuro Relief Ltd created the external combined occipital and trigeminal nerve stimulation (eCOT-NS, Relivion), which stimulates both the occipital and trigeminal nerves simultaneously. It has multiple output electrodes, which are placed on the forehead, stimulating the trigeminal supraorbital and supratrochlear nerve branches bilaterally, and over the occipital nerves in the

7th Iranian International Headache & 2nd joint Headache-Pain Congress

back of the head. It is worn like a crown around the head and it must be in good contact with the forehead and the back of the head simultaneously.

gammaCORE

The nVNS (gammaCORE, electroCore) is a noninvasive vagal nerve stimulation device that is FDA-cleared for acute and preventive treatment of migraine in adolescents and adults, and acute and preventive treatment of episodic cluster headache in adults. It is also cleared to treat chronic cluster headache acutely along with medication. The patient applies some gel to the device's two electrical contacts and then locates the vagus nerve on the side of the neck to be treated. Patients can adjust the stimulation's intensity so that they can barely feel the stimulation, but it has not been reported to be painful. nVNS is also cleared treatment of paroxysmal hemicrania and hemicrania continua.

SAVI Dual

s-TMS, (The SAVI Dual™ (formerly the Spring TMS™ and the sTMS mini™))

made by eNeura, is a single pulse, transcranial magnetic stimulation applied to the back of the head to stimulate the occipital lobes in the back of the brain. It is FDA-cleared for acute and preventive care of migraine in adults. The patient holds a handheld magnetic device against her occiput; when the tool is discharged, a brief magnetic pulse interrupts the pattern of neuronal firing (probably cortical spreading depression), that can trigger migraine and the visual aura associated with a third of migraine patients.

Cefaly

e-TNS (Cefaly, Cefaly-Technology) works by external trigeminal nerve stimulation of the supraorbital and trochlear nerves bilaterally in the forehead. It gradually increases in intensity and can be controlled by the patient. It is FDA cleared for acute and preventive treatment of migraine; unlike the other devices, it is sold over the counter without prescription. According to the company website, there are three devices, one for acute and one for preventive treatment, and one device has two settings, for acute and preventive treatment.

Methods: Data on each will be presented.

Results: All five of these devices have data showing superiority over sham treated patients

Conclusion: Electrical and magnetic stimulating devices are here to stay. They have been used for several years to treat headache patients. New devices are being FDA cleared whenever they are found safe and effective.