New Device for Stroke Survivors Wins FDA Approval

A system that uses vagus nerve stimulation helps people regain mobility in their hands and arms after an ischemic stroke.

September 13, 2021 By Jeanette L. Pinnace

Individuals who suffer an ischemic stroke frequently lose the ability to move their upper limbs. But a new device called the Vivistim Paired VNS System, which was recently approved by the Food and Drug Administration, could help restore stroke patients' hand and arm mobility, reports NewsMax.com.

An ischemic stroke occurs when an artery that carries blood to the brain is blocked, which reduces the flow of blood and oxygen to the brain. The serious condition accounts for 87% of all strokes.

A pulse generator, Vivistim is the first-of-its kind stroke rehabilitation system. Doctors implant the device under the skin of a patient's chest, where it transmits electrical impulses to electrodes placed on the left side of the neck, where the vagus nerve is located. Using clinician software preloaded on a laptop and a wireless transmitter, doctors record and monitor the electrical impulses and chart the history of stimulation, movements and other information to effectively control an individual's rehabilitation.

The FDA approved Vivistim following a clinical trial involving 108 U.S. and U.K. stroke patients. Scientists instructed participants to finish 300 to 400 exercises during a 90-minute period three times each week for six weeks and then applied vagus nerve stimulation to individuals in the treatment group. Another set of participants served as the control group and received only low levels of stimulation.

After three months of follow-up, 47% of patients treated with the system showed improved mobility in their arms and hands compared with 23.6% individuals in the control group.

Side effects of Vivistim use included bruising, falling, hoarseness, pain, depressed mood, headache, throat irritation and difficulty speaking.

Still, the positives seem to outweigh the negatives. "Used alongside rehabilitative exercise, this device may offer benefit to those who have lost function in their upper limbs due to ischemic stroke," said Christopher Loftus, MD, the acting director of the agency's Center for Devices and

Radiological Health’s Office of Neurological and Physical Medicine Devices.

Vivistim received the OK for use by stroke patients under the special “Breakthrough Device” designation, which is given to devices that treat or diagnose a life-threatening or irreversibly debilitating disease or condition and that meet one of the following conditions: the device represents a breakthrough technology; has no viable alternatives; offers significant advantages over approved alternatives; or is in the patient’s best interest.

To learn more about other therapies that were recently FDA-approved, read "FDA Approves Controversial Alzheimer’s Treatment" and “FDA Approves New Treatment for Highly Resistant Tuberculosis.”
