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MRI-Guided Ultrasound to Treat Tremor Gets OK From FDA

The U.S. Food and Drug Administration (FDA) has given the green light to a focused ultrasound device that uses magnetic resonance (MR) images taken during the procedure to treat essential tremor in patients who have not responded to medication.

ExAblate Neuro, manufactured by InSightec in Dallas, Texas, delivers focused ultrasound to destroy brain tissue in a tiny area thought to be responsible for causing tremors.

This new treatment option could help patients avoid more invasive surgical treatments, explained Carlos Peña, Ph.D., M.S., director of the division of neurological and physical medicine devices in the FDA's Center for Devices and Radiological Health.

Essential tremor, also known as 'benign essential tremor', is the most common form of condition that affects several million Americans, usually over the age of 40, according to the National Institute of Neurological Disorders and Stroke (NINDS).

Essential tremor may be treated with beta blockers or anticonvulsant drugs and if the symptoms are not controlled by medication, the condition may also be treated with surgery (thalamotomy) or a deep brain stimulation device to destroy the tiny part of the brain (thalamus) that controls some involuntary movements.

To determine if the ExAblate Neuro treatment is appropriate, patients should first have MR and computerised tomography (CT) scans, the FDA said.

Those undergoing treatment with the MRI-guided device lie in an MRI scanner that takes images to help a doctor identify the targeted area in the brain's thalamus for treatment. Treatment with transcranial focused ultrasound energy is administered with incremental increases in energy until patients achieve a reduction of

tremor.

Patients treated with the ExAblate Neuro showed nearly a 50 percent improvement in their tremors and motor function three months after treatment. At 12 months post-procedure, the treatment group retained a 40 percent improvement.

The FDA said that adverse events for the ExAblate Neuro are consistent with those reported for thalamotomy surgery, including numbness/tingling of the fingers, headache, imbalance/unsteadiness, loss of control of body movements (ataxia) or gait disturbance. Other side effects identified as possibly related to treatment with MR-guided focused ultrasound treatments include tissue damage in an area other than the treatment area, hemorrhage in the treated area requiring emergency treatment, skin burns with ulceration of the skin, skin retraction and scar formation and blood clots.

The ExAblate Neuro treatment is contraindicated for patients who cannot have MR imaging, including those who have a non-MRI compatible implanted metallic device, such as a cardiac pacemaker, those with allergies to MR contrast agents or those with body size limitations for MR.

Source: www.fda.gov

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