Non-Invasive Approach To Essential Tremor Treatment

(PRNewswire)

A new chapter in medical history opened days ago when noninvasive MR-guided focused ultrasound was used to successfully treat a patient with essential tremor (ET), a progressive neurological disorder that affects millions of people worldwide and causes involuntary shaking of the hands, head, face, eyelids, voice or other muscles. The procedure has been life-changing for the patient, says W. Jeffrey Elias, M.D., a neurosurgeon at the University of Virginia and a leading authority on the treatment of movement disorders.

"He had been unable to use his dominant right hand for over a decade because it shook uncontrollably. When we completed the treatment, his tremor was gone. In the recovery room, he used his right hand to drink from a cup without spilling, and he even worked on a crossword puzzle." Performed on February 25, 2011, the treatment marked the start of a first in the world clinical trial being funded by the Focused Ultrasound Surgery Foundation. The single-arm, non-randomized pilot study is being conducted at UVA and is expected to treat as many as 15 patients with ET under an FDA-approved protocol. Elias is the principal investigator.

During the MR-guided focused ultrasound procedure, pulses of focused ultrasound waves were directed through the patient's scalp and skull to a precisely targeted spot in the thalamus. The patient received no anesthesia for the treatment and was able to provide feedback to Elias and his team after each sonication. Following the treatment, he walked out of the focused ultrasound suite reporting that the sonications were painless.

Per study protocol, the patient remained in the hospital overnight and returned home the next day. A follow-up visit a week later indicated that his right hand was functioning normally. Additional follow-up assessments will occur 30 and 90 days post treatment, and Elias is hopeful that the patient's tremor will not return.

While excited about the dramatic outcome this first treatment, Elias cautions that it is only the initial step in a lengthy process. "We need to complete this study and other clinical trials successfully before this treatment is eligible for approval by the FDA and its counterparts in other countries," he notes. Chairman of the Focused Ultrasound Surgery Foundation Neal Kassell, M.D. says the success of this study could lead to other new treatments. "By demonstrating that MR-guided focused ultrasound can safely and effectively treat tissue deep in the brain with great precision and accuracy, we will open the door for treating a variety of conditions such as Parkinson's disease, brain tumors, and epilepsy.

To advance clinical research for ET, the Foundation is funding a second pilot study at Sunnybrook Health Sciences Center in Toronto. That clinical trial is scheduled to begin later this year under a Health Canada-approved protocol.

Current treatment options for ET range from medication to surgery. In the U.S., medication therapy provides satisfactory symptom control for many of the 10 million people with ET. For patients who do not respond to medication, the surgical procedures of choice are stereotactic thalamotomy or deep brain stimulation of the ventralis intermedius nucleus of the thalamus. The UVA study is the first step in determining if MR-guided focused ultrasound is a safe and effective treatment for ET and if it offers benefits beyond current surgical options.

The study is enrolling patients who are 18 to 80 years old and have completed trials of at least two ET tremor medications without success. Before and three months after treatment, participating patients are being assessed for general health, neurological status and tremor measurements. The study is also collecting data about any device/procedure-related side effects that occur during the follow-up period.

During treatment, patients are positioned on the ExAblate Neuro, a system manufactured by InSightec, Ltd. that has a specially designed table with a helmet-like head unit containing phased array focused ultrasound transducers. The table is placed inside a high resolution MR scanner that provides imaging for precise targeting. The scanner also provides thermal feedback to confirm and control sonication temperatures. Treatments are completely noninvasive and do not involve ionizing radiation.

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