FOCUSED ULTRASOUND THALAMOTOMY FOR ESSENTIAL TREMOR: CLINICAL STUDY RESULTS

Exablate Neuro

INSIGHTEC
FOCUSED ULTRASOUND THALAMOTOMY FOR ESSENTIAL TREMOR: CLINICAL STUDY RESULTS

BACKGROUND

Essential tremor can impact a patient’s quality of life and functional activities. If patients develop resistance to first-line medications, surgical interventions, like DBS or thalamotomy may be considered. Initial trials of thalamotomy using focused ultrasound with magnetic resonance imaging guidance in patients with essential tremor have shown a reduction in hand tremor and improvement in quality of life.

Here we present an overview of the multi-center pivotal clinical study of MRI-guided focused ultrasound thalamotomy for the treatment of medication-refractory essential tremor. For the complete Information for Prescribers, please visit http://www.accessdata.fda.gov/cdrh_docs/pdf15/P150038C.pdf.

METHODS

Patients with moderate-to-severe essential tremor who did not show a response to at least two trials of medication were randomly assigned (3:1) to unilateral focused ultrasound thalamotomy or sham procedure. After 3 months, patients in the sham-procedure group could cross over to active treatment.

Patients were assessed with The Clinical Rating Scale for Tremor (CRST) and the Quality of Life in Essential Tremor Questionnaire (QUEST) at baseline and at 1, 3, 6, and 12 months. Tremor assessments were videotaped and rated blindly by an independent group of neurologists.

Primary outcome was change from baseline to 3 months in the tremor score, derived from CRST Part A and Part B. Secondary measures were function in daily activities, derived from the disability sub-section of CRST, quality of life assessed with QUEST at 3 months and durability of hand tremor reduction at 12 months.

RESULTS

The study participants (n=76) had a mean age of 71.1 years and most had a family history of tremor (75%). Baseline tremor and demographics did not differ significantly between the groups.

HAND TREMOR. The composite score (CRST Part A and B) for the focused ultrasound thalamotomy group improved by 46.9% (from 18.1±1.3 points at baseline to 9.6±1.4 at 3 months) and by 0.1% in the sham group at 3 months. The thalamotomy group maintained a 40% improvement at 12 months, which was not statistically different from the 3 month score. The posture component of CRST Part A is presented on the next page.
FUNCTIONAL DISABILITY AND QOL. Total disability score (CRST Part C) for the treatment group significantly improved from baseline to 3 months (63% reduction) as compared to sham (2% reduction). The improvement for the thalamotomy group was sustained at 12 months. Patient reported quality of life (QUEST) scores also improved significantly (43% reduction) as compared to sham (5% reduction).

SAFETY. All but one of the reported adverse events found to be thalamotomy-related were mild or moderate. The most common persistent adverse events were numbness/tingling (12%), imbalance (5%), unsteadiness (2%), and gait disturbance (2%). Overall, the study showed a very favorable safety profile.

FOR MORE INFORMATION, PLEASE REFER TO:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm510521.htm
ABOUT EXABLATE NEURO
Exablate Neuro is a non-invasive, image-guided thalamotomy, performed through an intact cranium that doesn’t require any radiation, incisions or implants.

Focused ultrasound energy is precisely delivered to a focal point in the Vim nucleus of the thalamus. Prior to the delivery of high temperatures, low energy sonications are used to identify the target, evaluate patient response and make adjustments before creating a permanent lesion.

Ablation of the target occurs at a temperature above 56°C for a highly accurate and a controlled thermal effect.

MRI provides high resolution visualization, patient-specific treatment planning and continuous monitoring of the procedure for a very favorable safety profile.