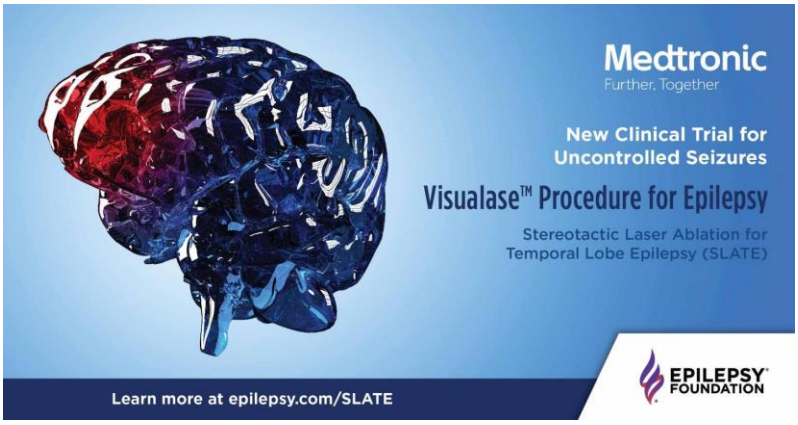

Study Title: Stereotactic Laser Ablation for Temporal Lobe Epilepsy

What is this study about?

This study is looking at the safety and efficacy of MRI-guided laser ablation therapy with Visualase™ (laser ablation may also be called laser interstitial thermal therapy or LITT), for seizures coming from the temporal lobe in people who are taking seizure medicines. In this study, the Visualase procedure is given in addition to participants' current anti-seizure medications and/or VNS Therapy® (vagus nerve stimulation).

The study will look at a number of outcomes, including whether people have fewer seizures or become seizure free one year after the procedure. The study will also review whether participants have a change in their mood, quality of life, and/or memory after one year.

Who can participate?

To be part of this study, people must:

- Be 18 or older and less than 70 years old.
- Still have uncontrolled epileptic seizures, even though you have tried at least two anti-epileptic drugs.
- Have had at least 12 seizures in the last year.

People cannot be part of this study if:

- They are pregnant or intend to become pregnant prior to the procedure.
- They have an implanted device that can interfere with MRI testing. These devices include a responsive neurostimulator (RNS) or deep brain stimulator (DBS).
- They have progressive brain lesions or tumors not associated with their epilepsy.
- They have a history of previous brain surgery for treatment of epilepsy, including intracranial resections, stereotactic radiosurgery, or deep brain stimulation.
- They have an active major psychiatric illness, nonepileptic seizures, or medical illness that would make the Visualase procedure unadvisable or affect the memory assessments.

EPILEPSY FOUNDATION

How can I participate?

- Interested people will be screened to confirm eligibility for enrollment.
- A review of the person's epilepsy history, MRI (a non-invasive imaging scan showing the structure of the brain), and EEG will be performed to confirm study qualification for the Visualase procedure.

If you are eligible for this study (SLATE):

- Before the Visualase procedure, you will have mental and cognitive function tests, an eye exam, and an MRI scan.
- You will have the Visualase procedure. The Visualase procedure is performed in the hospital under general anesthesia (you will be asleep), and most participants stay in the hospital for one night before going home.
- You will return four times over 12 months for check-ups, mental and cognitive function tests, eye exams, and MRI scans.
- You will be asked to track seizures in a diary before and after the procedure.

Study participants must be willing to:

- Take anti-epileptic drugs as prescribed.
- Complete a daily seizure diary.
- Complete the required testing and follow-up visits.

Are there risks?

- With all trial drugs and devices, there is the chance the treatment may not help a person's seizures.
- Risks associated with the Visualase procedure include: visual field loss, blurry sight, seeing double, anesthesia effects, infections, bleeding, edema, headaches, healing complications, back pain, cerebrospinal fluid (CSF) leakage, memory difficulties, and depression.

For more information, visit www.medtronic.com/SLATE, clinicaltrials.gov, or contact rs.slatestudy@medtronic.com.