

Established Status Epilepticus Treatment Trial (ESETT)

A prolonged seizure affects individuals of all ages, from the very young to the elderly.

Status Epilepticus (SE) is a life-threatening condition in which the brain is in a state of persistent seizure. SE is defined as a seizure or recurrent seizures lasting longer than five minutes without stopping on its own or without waking up. A person whose seizure does not stop even after receiving a full dose of medicine (benzodiazepines) is considered to have Established Status Epilepticus (ESE).

There are approximately 120,000 - 180,000 episodes of SE each year in the US. About one third of SE patients continue to have a seizure that will not stop, or ESE.

Long-lasting seizures can affect a person's ability or think and remember things. It can prevent a person from returning to work or functioning independently. Seizures can cause permanent brain damage or even death.

ESETT is a research study designed to try to save and improve the lives of people who experience established status epilepticus (ESE). Emergency department care of patients with a long-lasting seizure in the US is not the same everywhere. Doctors use their judgement, but what treatment will work best is not known. This study plans to look at three commonly used medicines given in the emergency departments for ESE: phenoytoin (fPHT), valproic (VPA), and levetiracetam (LVT) to learn which treatment is most effective at stopping a seizure quickly.

Normally, researchers get permission before a person can be included in a study. However, a person having a seizure will not be able to give consent. Since a seizure that will not stop on its own must be treated quickly, there will not be enough time to locate and talk to the person's legal representative about the study, so the person will be enrolled in the study without his/her legal representative's consent. This is called "Exception from Informed Consent" (EFIC). Once the representative is located or the patient wakes up, they will be asked to give their permission to continue in the study.

The purpose of this handout is to notify our community about this trial, and to provide contact information and resources for you to learn more, including an option to decline participation.

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