How can I share my opinions about this study?

Before the study starts, meetings will be held in the community to provide information, answer questions and get community members' thoughts and feelings about the study. You can call the study team to complete a one-on-one interview about the study. There will also be information about the study in the media (for example, newspapers, TV and radio).

What if I do not want to be included in the study?

There are two methods for opting out:
1. Through a Medic Alert™ membership. If you have an existing medic alert tag or bracelet you can add "ESETT Study Declined" to it. If you have a medic alert membership you can add "ESETT Study declined" to your Emergency Medical Information Record. If you would like to find out more information about your existing medic alert services or for a new membership visit: www.medicalert.org

2. Call us to request an **Opt Out bracelet** be sent to you to wear with the words "ESETT declined". You will need to wear this bracelet at all times during the study period (approx.5 years), or else you could be enrolled.
If you do not participate in the study, you will receive the standard medical treatment provided for established status epilepticus at the hospital in your community.

Where can I learn more about the study?

Online at: www.esett.org
Or, if you would like to know about a community meeting near you or to get more information about the ESETT study, contact a local study team member (on the back).

Contact Us

ESETT Study
Yale-New Haven Hospital
New Haven, CT 06519
Phone: 203-785-2353
E-mail: ESETT@yale.edu

NETT & PECARN Networks

The ESETT study is part of the **Neurological Emergencies Treatment Trials (NETT) and PECARN Networks**. Both Networks are funded by the National Institutes of Health, an agency of the federal government.

NETT & PECARN conduct studies to learn how to improve emergency care for severe injuries and illnesses of the brain, spinal cord, and nervous system in adults and children.

Both Networks include 39 institutions across the county and their surrounding hospitals. The following hospitals that will be participating in ESETT in this area include:

- Massachusetts General Hospital
- Yale-New Haven Hospital
- Rhode Island Hospital
- Hasbro Children's Hospital

The research study has been reviewed by the Yale University Human Research Protection Program.
IRB approval number: 1504015625

ESETT

Established **S**tatus **E**pilepticus **T**reatment **T**rial

Learn about ESETT: a seizure study that may affect you or someone you know.

A research trial conducted by
The Neurological Emergencies Treatment Trials (NETT) Network
&
Pediatric Emergency Care & Applied Research Network (PECARN)

www.esett.org

What is SE?

Status Epilepticus (SE) is defined as a seizure or recurrent seizures lasting longer than five minutes without stopping or waking up. A person whose seizure does not stop after receiving a full dose of medicine (benzodiazepines) to make it stop is considered to have Established Status Epilepticus (ESE).

A prolonged seizure can:

- Happen to someone of any age
- Affect one's ability to think and remember
- Prevent a person from being able to function normally or independently
- Limit awareness and cause coma
- Cause permanent brain damage
- Cause death

What is ESETT?

Emergency department care of Established Status Epilepticus (ESE) in the US is not the same everywhere. Doctors use their judgment, but what treatment will work best is not known. The purpose of this study is to find out which of three commonly used medicines given in the emergency department for (ESE) is safer and more effective.

- fosphenytoin (fPHT),
- valproic acid (VPA), and
- levetiracetam (LVT)

Why do this study?

The best possible outcomes in patients with Established Status Epilepticus (ESE) are likely to depend on a treatment that rapidly stops their seizure.

Who will be included?

- Any patient who is 18 years or older with an
- Active recurrent or ongoing seizure lasting longer than five minutes, and
- Has already received an adequate dose of benzodiazepine (like valium) in the past 5-30 minutes to make the seizure stop could be enrolled.

To start 1/3 of all study participants will randomly receive fPHT, 1/3 VPA and 1/3 LVT. After the study medicine is given, blood samples may be taken to measure the amount of study drug in the blood.

As the study goes on, a higher proportion of patients will be randomized to the drug or drugs which better stop seizures.

If the seizure does not stop doctors will follow their normal procedure and give extra medication to make it stop.

The extra medicine could be one of the three medicines being studied or a different medicine.

What are the benefits?

Because we do not know which treatment is best for treating Established Status Epilepticus, a person enrolled in the study may receive a better medicine to treat their seizures.

Based on the information we get from this study, people who have a seizure in the future may benefit from what is learned from this study.

What are the risks?

There are risks to receiving the study drugs. The risks of the study drugs are similar to those that a patient might have if they receive treatment for their seizures outside of this study.

How is enrollment in ESETT different from other studies?

Normally, researchers get permission before a person can be included in a study. 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. All patients will be enrolled in the study without his/her legal representative's consent. This is called "**E**xception **f**rom **I**nformed **C**onsent" (**EFIC)**. Once the representative is located or the patient wakes up, they will be told about the study and asked to give their permission to continue in the study.

What is EFIC?

The U.S. Food and Drug Administration (FDA) is an agency of the federal government that oversees human research protection involving medicines. The FDA has created a set of special rules, called "Exception from Informed Consent" (EFIC). These special rules allow research studies in certain emergency situations to be conducted without consent.

EFIC can only be used when:

- The person's life is at risk, AND,
- The treatments we have don't work, AND
- The study might help the person, AND
- It is not possible to get permission:
  - from the person because of his or her medical condition nor
  - from the person's guardian because there is a very short amount of time required to treat the medical problem

Before researchers may do a study using EFIC, they must provide information about the study to the community and get their feedback.