

ESETT Rick/Benefit Public Announcement

Public Notification For An Emergency Research Study of Seizures in Milwaukee County, WI

Researchers at the Medical College of Wisconsin are studying the best way to treat long seizures.

This notice is to inform you of a research study looking at medicines to treat long seizures. The study will begin at Froedtert Hospital and Children's Hospital of Wisconsin in January 2016. Researchers will compare three medicines used to treat long seizures to decide which medicine is best at stopping a long seizure. The goal of this research is to improve the lives of people who have long seizures.

What is a long seizure?

A seizure, usually seen as a fit of uncontrolled movements, is caused by abnormal brain activity. Doctors consider a seizure a long seizure when the seizure lasts longer than five minutes without stopping on its own or without the person waking up. A person whose seizure does not stop even after receiving a full dose of medicine that can stop seizures (benzodiazepines) has a long seizure. This means that doctors need to use other medicines besides benzodiazepines.

Why do we need to do this research?

Emergency department care of patients with a long seizure in the United States is not the same everywhere. Doctors typically use their best medical judgment about which medicines to use after benzodiazepines do not work. However, which of the medicines will work best is not known. This study will compare three commonly used medicines given in emergency departments for long seizures. These three common medicines are fosphenytoin, valproic acid, and levetiracetam. Researchers will learn which treatment is best at stopping a long seizure quickly. All of these medicines are already being used for seizures in children and adults. Each person will receive one dose of one of the study medicines. Which medicine a person receives is decided by chance. Patients will receive all other standard treatment for seizure.

Are there risks to this research?

All research has risks. The study medicines work in different ways and have different risks. The risks of the study medicines are the same whether they are given in the study or for treatment of seizures outside of the study. Possible side effects of any of the medicines include drowsiness, dizziness, allergic reaction, or pain, discomfort, or inflammation where you got the injection in the vein. In addition, fosphenytoin may cause low blood pressure, slow heart rate, inflammation of blood vessels, or skin rash. Levetiracetam may cause behavior changes such as nervousness, confusion, or aggression. Valproic acid could cause a skin rash and liver or pancreas problems. Every precaution will be taken to assure personal safety. All information obtained from this study will be kept private. The findings from this study will be shared at meetings and in scientific journals to help others. Information that could identify a person will not be used.

What is the benefit of this research?

Because we do not know which of the commonly used medicines is better, people may benefit from receiving a better medicine, but this is not guaranteed. The information may lead to better treatments for long seizures in the future. People will not receive money for being in this research study and it will not cost a person anything.

Adults and children over the age of 2 treated for long seizures at Froedtert or Children's Hospital of Wisconsin Emergency Departments may be in this study.

Normally, researchers get permission before a person can be included in a research study. A long seizure is an emergency and the doctors have to act quickly to treat a person. This means that there is little time to get permission. Researchers will discuss the study with the patient or family as soon as possible. A person having a seizure is unconscious and cannot agree to join. In studies like this, a person's consent before treatment is not possible. This is called an exception from informed consent for emergency circumstances. That means, if you do not want to be in this study, you must request that you not be included. For more information on how to opt out see "opting out of this study" below. You will still receive regular treatment. Because doctors commonly use these three medicines for seizures, you may still receive the same medicine as what is used in the study. The U.S. Food and Drug Administration requires that researchers notify communities in cases when consent is not possible due to an emergency (FDA Code of Federal Regulations, Title 21, Section 50.24). We are notifying you before the study begins in January 2016. This study will continue for approximately 4 years.

Opting out of this study

Any adult who does not wish to be enrolled in this study may opt-out by wearing an opt-out bracelet or necklace. These may be requested free of charge by calling (414) 805-6493 or emailing ESETT@mcw.edu. Any parent/guardian of a child 17 years and younger that does not wish their child to be enrolled in this study may call (414)-805-6493 or email ESETT@mcw.edu to discuss the opt-out options.

Please contact us if you have any questions or concerns

If you have questions or concerns about this study or you do not want to participate, please contact Dr. Tom Aufderheide or Dr. Danny Thomas, either by phone (414-805-6493), mail (Department of Emergency Medicine, 9200 W. Wisconsin Ave., Froedtert Hospital East, PV1, Milwaukee, Wisconsin 53226) or email (ESETT@mcw.edu), or visit the web site at (www.mcw.edu/ESETT). Feedback from the community may be used to change the study.