National trial to assess drugs for severe seizures

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Researchers at Washington University School of Medicine in St. Louis are part of a national clinical trial to assess medications for patients brought to emergency rooms to receive treatment for prolonged and dangerous seizures. Credit: Thinkstock

Questions remain regarding how best to treat patients experiencing

prolonged, dangerous seizures. Although emergency medical teams around the country use a variety of approaches, more research is needed to give patients the best chance of surviving and to prevent or limit brain damage.

A new clinical trial involving Washington University physicians at St. Louis Children's Hospital will compare three commonly used anti-seizure medications used to treat seizures that last over five minutes and don't respond to initial treatment—a condition called established status epilepticus (ESE). Such seizures can strike anyone but are most common in people already diagnosed with epilepsy.

St. Louis Children's is among 14 pediatric medical centers nationwide to participate in the study.

For years, doctors have used these three drugs to treat seizures in children: fosphenytoin, also called Cerebyx; levetiracetam, also called Keppra; and valproic acid, also called Depakote.

"In the emergency setting, we do not know which medicine works best for treating the prolonged seizures," said the study's primary investigator, Sri Chinta, MBBS, an instructor in pediatrics at Washington University School of Medicine in St. Louis and an emergency pediatrician at St Louis Children's. "We should identify treatments that result in the best possible outcomes for patients with status epilepticus. People whose seizures cannot be stopped often die or suffer permanent brain damage."

All three medicines are approved by the Food and Drug Administration (FDA) for the prevention of seizures, but levetiracetam and valproic acid have not been FDA-approved to treat prolonged seizures. And while fosphenytoin has been approved to stop prolonged seizures in adults, it is not FDA-approved for use in children.

Patients ages 2 to 17 who arrive at St. Louis Children's Emergency Department with ongoing seizure activity despite initial treatments will be enrolled and randomly assigned to receive one of the three study medications.

The study is double-blinded; neither patients nor physicians will know which medication a patient will receive.

As these seizures require immediate clinical intervention, patients will be given study medications using "exception from informed consent" (EFIC) so that treatment is not delayed.

National EFIC rules allow research studies in certain emergency situations, such as this one, to be conducted without patient or parental consent.

"Every second counts when treating patients with severe, ongoing seizures," said Liu Lin Thio, MD, PhD, an associate professor of neurology, of pediatrics and of neuroscience at the School of Medicine. "We must act immediately to give patients the best chance of controlling their seizures."

Because the trial involves children, a parent or legal guardian will be given details about the clinical trial following enrollment and asked for permission to allow that patient to continue in the study. Researchers also will ask patients 12 and older if they would like to continue participation. If permission is granted, patients will be monitored until hospital discharge or for 30 days.

To broaden awareness about the study, the Washington University Institutional Review Board approved a community consultation and public disclosure plan to inform St. Louis-area residents about the study and obtain feedback before the trial begins.

Ongoing efforts include speaking to community organizations, placing posters and flyers in local businesses and garnering attention through social media to reach larger audiences.

While the researchers are hopeful that the community will be receptive to this trial, called the Established Status Epilepticus Treatment Trial, there are options for those wishing to opt out of the trial. These include:

- Adding "ESETT Study Declined" to a medical alert tag or bracelets.
- Wearing an opt-out bracelet with the words "ESETT declined." To obtain bracelets, visit the Established Status Epilepticus Treatment Trial website at www.esett.org or call 314-454-2341.

The School of Medicine, which will conduct the study through 2020, is one of 44 sites nationwide participating in the clinical trial. Altogether, researchers will enroll more than 700 patients.

Provided by Washington University School of Medicine in St. Louis

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