

## What is the Pediatric Seizure Study?

By the age of 15, four to eight percent of children have had a seizure episode.

A team of 11 children's hospitals across the country is conducting the Pediatric Seizure Study to learn which of two commonly prescribed medicines is best for treating seizures in children in the emergency room (ER).

## Why are we doing the study?

We are conducting this study because it is important to test which medications are best for pediatric seizure patients.

Both Lorazepam and Diazepam are commonly prescribed by doctors for treating seizures in children. Lorazepam has been approved by the Food and Drug Administration (FDA) for adults, but has not yet been approved for children. Doctors have been able to use Lorazepam "off-label" to safely treat children for years.

"Off-label" means the medication's label does not specifically say that it can be used in children. Doctors can use their best judgment to prescribe any FDA approved medication for any patient. Off-label use is very common in children because many drugs are not widely studied in children before they are approved for use.

Lorazepam and Diazepam are both effective in treating seizures, but both may cause slowed breathing, a condition called respiratory depression. Currently doctors do not know which one is better. At the end of this study, doctors hope to know which medication is better to treat seizures in children.

## How would children be enrolled in the study?

Seizure medication has to be given within five minutes of a child's arrival in the ER so there might not be enough time to talk to a child's parent/guardian about the study. In that case, a child may be enrolled in the study without a parent present.

If a child is seizing when he or she arrives in the ER, a doctor will evaluate the child to see if he or she qualifies for the study. If the child qualifies, he or she would be enrolled in the study automatically and would get one of the two medicines chosen at random. This is similar to the way children are treated now, because both Lorazepam and Diazepam are commonly prescribed. The only difference is that the medication would be chosen at random, not by the doctor.

After the doctor has made sure that the child has been treated medically, the doctor or a representative from the study team will contact the parent to let them know that his/her child has been enrolled in this study. At this time, the parent will be given all of the details about the study and can choose to continue or refuse the child's participation.

## What are the benefits of participation?

Because we do not know which medicine is better, a child may benefit from receiving a better medicine. The child also will receive extra medical monitoring beyond regular medical care. This includes our medical team taking extra vitals signs and other physical examination assessments.

## What are the risks of participation?

There are very few risks of participating in this study. The medical staff have received extensive training about proper administration of these particular medications. Every healthcare provider is committed to providing the safest environment for all children in the ER.

The medication being studied is already used to treat children with seizures. Lorazepam and Diazepam have similar side effects, such as respiratory depression, sleepiness, muscle cramps, anxiety, dizziness, and visual hallucinations. The healthcare team will monitor your child for side effects.

Study participation also includes getting small blood samples from the child, but the staff would not do that without permission. The last part of the study is a telephone interview 48 hours and then 30 days after the child is enrolled. We would not call the parents without their permission.

As part of this study, parents would not be required to return to the hospital for any additional visits – the telephone interview would end the child's participation in this study.

## What if I do not want my child to participate?

Call us or visit our web site to fill out a refusal form if you do not want your child to participate in the study. Your child will still receive the best possible care if he or she comes to the emergency room with a seizure.

## Who may be enrolled in the study?

Children between the ages of 3 months to 18 years of age with prolonged seizures who are treated in the participating hospitals' emergency rooms may be included in this study.

## Where can I learn more about the study?

Before the study starts, some sites will hold community meetings to provide information, answer questions and obtain community feedback about the study. For a schedule of meetings, please contact us or visit our web site.

## How do I give my feedback?

You can call, send comments through our web site or write to us. ***We want to hear your opinions about this study!***

## Will I be compensated for participating?

Compensation will vary depending on the participating hospital.

## Contact Us

### Pediatric Seizure Study

Children's National Medical Center  
Emergency Room  
111 Michigan Avenue, NW  
Washington, DC 20010

[www.dcchildrens.com/seizurestudy](http://www.dcchildrens.com/seizurestudy)  
1-866-377-8557

## Participating Centers

**Children's National Medical Center**  
Washington, DC

**Children's Hospital of Philadelphia**  
Philadelphia, PA

**University of California**  
Davis, CA

**Children's Hospital of Michigan**  
Detroit, MI

**Children's Hospital of Buffalo**  
Buffalo, NY

**University of Michigan**  
Ann Arbor, MI

**University of Maryland Medical Systems**  
Baltimore, MD

**Children's Hospital of Wisconsin**  
Milwaukee, WI

**Children's Hospital Boston**  
Boston, MA

**Primary Children's Hospital**  
Salt Lake City, UT

**University of Rochester Medical Center**  
Rochester, NY



# Does Your Child Have Seizures?

*Learn more about a seizure study that may be happening in the emergency room at your hospital.*



**The Pediatric Seizure Study**