Pharmacokinetics and dosing of diazepam for children experiencing severe seizures

WHY WAS THIS STUDY NEEDED?

Diazepam is a medicine approved by the U.S. Food and Drug Administration (FDA) for treating severe seizures in children. However, the most safe and effective dosage of diazepam for children was unknown. A study called "Efficacy and Safety Study Comparing Lorazepam and Diazepam for Children in the Emergency Department With Seizures" provided data that were analyzed by the Pediatric Trials Network (PTN) to learn the best dose of diazepam to give children with severe seizures. This analysis was also needed to learn how long diazepam stays in the bodies of children of varying ages and weights. This information is important because seizures must be treated quickly, and an incorrect amount of diazepam can cause negative effects, such as slowed breathing.

Pharmacokinetics is the study of how our bodies process medicines. Understanding pharmacokinetics makes sure that children receive the right amounts of medicine.

WHAT WERE THE STUDY RESULTS?

The PTN used the study data to develop a formula for diazepam dosage based on children's weight. In most participants, seizures stopped for at least 10 minutes within 30 minutes of the first dose. Some participants experienced slow breathing and required a machine to help them breathe.

WHAT HAPPENED NEXT?

Results from the PTN's analysis were submitted to the FDA to update the label for diazepam. A medicine's label contains information for health care providers to use when prescribing it. The new label includes data and guidance for dosing diazepam based on children's body weight.

To date, this was the largest study of diazepam in children with severe seizures, and it was the first study to create a formula for how children process the medicine. Future studies are needed to learn more about the most effective dose of diazepam for treating seizures in children. Future studies should also include newborns and children with organ dysfunction to learn how age and organ function affect diazepam treatment.

WHAT KIND OF STUDY WAS THIS?

The PTN analyzed data from a study that tested how children process diazepam. It learned how much diazepam to give patients to reach the most effective amount in their body for treating seizures. The study took place across 11 children's hospitals in the United States. Researchers studied diazepam in 87 children, aged 3 months to 17 years, who came to the emergency room with severe seizures.

WHAT HAPPENED DURING THIS STUDY?

Participants received diazepam through an injection to treat their seizures. If seizures continued, participants received a second dose of diazepam. Researchers tested the participants' blood to see how much diazepam was in their body over time.

WHO PERFORMED THIS STUDY?

Data from this study were analyzed by the PTN, a group of more than 100 research sites around the world that work to find the safest, most effective ways to use medicines and devices for infants and children. Children aren't just little adults. Their bodies are growing and changing, meaning that they process medicines and react to devices different from adults. The PTN makes sure doctors and families have the information they need to give children the best care.

This study was made possible with support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

A summary of the results of this study, as well as related publications and news, can be found at pediatrictrials.org.

** This summary was completed in October 2024. Newer information since this summary was written may now exist. This summary includes results from one PTN study. Other studies may find different results.*

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