

Lorazepam in children with status epilepticus



WHY WAS THIS STUDY NEEDED?

Status epilepticus (SE) is a serious condition that affects the brain. SE can be caused by medical conditions, illnesses, or injuries. Patients with SE experience long-lasting and repeated seizures that can be life-threatening. A preferred treatment for SE is lorazepam. However, lorazepam is not approved by the FDA for children under 18 years old. This summary is for a study performed by the Pediatric Trials Network (PTN). The study was titled "[Population Pharmacokinetics and Exploratory Pharmacodynamics of Lorazepam in Pediatric Status Epilepticus](#)." The study was needed to find out how children with SE process lorazepam.

WHAT WERE THE STUDY RESULTS?

Researchers identified doses of lorazepam that children can process similarly to adults. The adult doses are known to control seizures. However, the children's data did not clearly show that lorazepam was effective.

WHAT HAPPENED NEXT?

PTN submitted the data from this study to the FDA to change the label for lorazepam. A medicine's label has the necessary information for health care providers to use when prescribing it. The new label now includes text explaining that research does not show lorazepam as an effective treatment for SE in children.

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.

WHAT KIND OF STUDY WAS THIS?

Pharmacokinetic studies are done to find out how the human body processes medicines. In this study, researchers examined how the amount of lorazepam in the children's blood changed over time compared to the dose they received. Understanding how children with SE process lorazepam will ensure they receive the right amount to treat their seizures.

WHAT HAPPENED DURING THIS STUDY?

This study used data from 2 previous studies in which children with SE received lorazepam to treat seizures. The data set included 145 children aged between 3 months and less than 18 years. With these data, researchers calculated how children process lorazepam compared to how adults process lorazepam.

WHO PERFORMED THIS STUDY?

This study was conducted by the PTN, a group of more than 100 research sites around the world that are working to find the safest and 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 differently than adults. The PTN works to make 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.

** This summary was completed in December 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.*



**PEDIATRIC
TRIALS NETWORK**

Making drugs safer & more effective
for use in the youngest patients