Evaluation of the ideal dosage of topiramate for children with and without obesity



WHY WAS THIS STUDY NEEDED?

Topiramate is a medicine used to treat seizures in adults and children. The recommended amount of topiramate children should receive is based on their weight. However, it was not known whether a child's obesity status affects how they process topiramate.

In the United States, 1 in 5 children have obesity. Doctors consider children obese when they have excess body fat that can cause a risk to their health. Researchers performed this study to learn how children with obesity process topiramate compared to children without obesity. They also wanted to learn the safest, most effective amount of the medicine they should receive.

This research used data from two PTN studies: Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care (POP01) and Pharmacokinetics of Anti-epileptic Drugs in Obese Children (AED01).

WHAT KIND OF STUDY WAS THIS?

This was a pharmacokinetics study to learn how children with obesity process topiramate compared to children without obesity. Pharmacokinetics is the study of how our bodies process medicine.

The study looked at data from 43 children aged 2-18 years. Most children in this study had obesity.

WHAT HAPPENED DURING THE STUDY?

Children who participated in the study were already prescribed topiramate by their doctors to treat seizures. Then, researchers tested their blood to see how much topiramate remained in their bodies over time.

WHAT WERE THE STUDY RESULTS?

The study found that the existing, weight-based dosing recommendations for topiramate can be used for children with obesity in addition to children without obesity. Changing the dose according to obesity status is not necessary.

WHAT HAPPENED NEXT?

The PTN submitted the data to the U.S. Food and Drug Administration (FDA), which led to an update to the topiramate label. The updated label now includes information about how children with obesity process topiramate as well as the recommendation that prescribers do not need to adjust the dosage based on obesity status.

A drug's FDA label contains necessary information for health care providers to use when prescribing it.

WHO PERFORMED THIS STUDY?

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, performed this study. 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.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development supported this study.

WHERE CAN I LEARN MORE ABOUT THIS STUDY?

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

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** This summary was written in August 2026. Newer information since this summary was written may exist. This summary includes results from two PTN studies. Other studies may find different results.*