Pharmacokinetics of oxcarbazepine in children with obesity

WHY WAS THIS STUDY NEEDED?

Oxcarbazepine is a medicine that is approved by the U.S. Food and Drug Administration (FDA) for treating seizures in adults and children older than two years. Recommendations for how much of the medicine a child should receive are based on their age and body weight. However, guidance for children who have obesity was lacking. Body weight is a factor that can change how a child processes medicine, and 1 in 5 children in the United States have obesity. Children are considered to have obesity when they have excessive fat that can cause a risk to their health.

This study by the Pediatric Trials Network (PTN), called Pharmacokinetics of Anti-epileptic Drugs in Obese Children (AED01), was needed to learn how a child's obesity status affects the way they process oxcarbazepine. It also learned how much oxcarbazepine health care providers should give to children who have obesity and are experiencing seizures.

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?

Researchers found that the existing dosing recommendations for oxcarbazepine in pediatric patients are effective for children who have obesity. Therefore, health care providers can follow the same dosing recommendations for children of average weight and those who have obesity.

WHAT HAPPENED NEXT?

Researchers submitted this data to the FDA to update the label for oxcarbazepine. A medicine's label contains necessary information for health care providers to use when prescribing it. The updated oxcarbazepine label includes guidance for dosing the drug for children who have obesity. The label change applies to the drug in both the form of a pill and liquid.

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?

This was a pharmacokinetic study to learn how children with obesity process oxcarbazepine. Data from PTN's study called Pharmacokinetics of Understudied Drugs Administered to Children per Standard of Care (POP01) were also used in this study. Researchers studied oxcarbazepine in 100 children and adolescents. Their ages ranged from 44 days to 20 years. Half of the participants studied had obesity.

WHAT HAPPENED DURING THIS STUDY?

Participants took oxcarbazepine by mouth as part of their treatment for seizures. Researchers tested the children's blood to see how much oxcarbazepine was in their bodies and how much remained over time.

WHO PERFORMED THIS STUDY?

This study was performed 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.

** This summary was completed in November 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