Pharmacokinetics of Clindamycin in Children, from Premature Infants to Adolescents



WHY WERE THESE STUDIES NEEDED?

Clindamycin is an antibiotic medicine that is often given to children to treat infections like methicillin-resistant Staphylococcus aureus (MRSA). In the neonatal intensive care unit, MRSA infection is associated with severe outcomes and high rates of death. Despite its common use in children, there is little information on the pharmacokinetics, how the drug is processed, of clindamycin in pediatric groups. These studies were needed to learn the safest, most effective dosage of clindamycin in children ranging in age from premature infants to adolescents.

WHAT KIND OF STUDIES WERE THESE?

This summary describes two studies that determined the pharmacokinetics and best dosage of clindamycin in children across age groups. One study examined how clindamycin was processed in a group of 21 premature infants. The other study tested the drug in 125 children, who had a median age of 3.3 years.

WHAT HAPPENED DURING THE STUDIES?

Both studies gave clindamycin to children being treated for infections like MRSA. Blood samples from the children were used to determine how the drug was processed in their bodies. Both studies also pulled in already-existing data on clindamycin in children to inform disposition across age groups. Safety of clindamycin was also assessed, and any negative side effects were recorded.

WHAT WERE THE STUDY RESULTS?

Each study resulted in pharmacokinetic data that are able to characterize how clindamycin is processed in the body across pediatric age groups. Providers prescribing clindamycin should consider a pediatric patient's age and body weight when deciding the dosage. Clindamycin was generally well-tolerated across participants, and any negative outcomes were not found to be associated with the drug.

WHAT HAPPENS NEXT?

Further studies are needed to determine other variables that may impact how pediatric patients process clindamycin.

The results of this study were sent to the U.S. Food and Drug Administration (FDA). The findings were used to change this medicine's "label," or the printed information that is included along with the drug. The findings were also published in scientific journals. Both the label and publications can provide doctors with information to help them give the safest, most effective dose of clindamycin to children.

WHERE CAN I LEARN MORE ABOUT THESE CLINICAL TRIALS?

A summary of the results for these trials can be found at <u>pediatrictrials.org</u>.

WHO CONDUCTED THE STUDIES?

The study was conducted by the Pediatric Trials Network (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.

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* This summary was completed in October 2023. Newer information since this summary was written may now exist. This summary includes only results from two PTN studies. Other studies may find different results.

