

AN OPEN-LABEL STUDY TO DESCRIBE THE PHARMACOKINETICS OF ACYCLOVIR IN PREMATURE INFANTS



WHY WAS THIS STUDY NEEDED?

Infants are at high risk for infections caused by bacteria and viruses. Herpes simplex virus (HSV) is a dangerous infection that can often cause death or mental disability in infants. Acyclovir is a medicine approved by the U.S. Food and Drug Administration (FDA) for HSV but the best and safest dose of acyclovir for infants, particularly premature infants, was not known.

32
PREMATURE
INFANTS



WHAT HAPPENED DURING THE STUDY?

The study was conducted at two sites — Duke University Medical Center in Durham, North Carolina, and Wesley Medical Center in Wichita, Kansas. Site teams enrolled 32 patients over the 9-month study. Acyclovir was administered to the infants to determine the levels of medicine in each.

WHAT WERE THE STUDY RESULTS?

Researchers found that older, more mature infants require a higher dose of acyclovir than younger, less mature infants.

WHAT KIND OF STUDY WAS THIS?

This study looked at the safety and pharmacokinetics dosing of acyclovir in infants who were suspected of having an infection. Thirty-two infants, less than one month old were involved in the study.

Pharmacokinetic studies find out how much of a drug gets into the body, where it goes, and how long it takes for the body to get rid of it.

WHAT SIDE EFFECTS DID ACYCLOVIR HAVE?

Overall, acyclovir was safe in this group of infants.

WHAT HAPPENS NEXT?

The results of this study were sent to the U.S. FDA, a government agency that approves drugs and devices used to treat patients. Our findings were used to change this medicine's "label," or the printed information that is included along with the drug. The findings will also be published in scientific journals. Both the label and publications can provide doctors with information to help them give the safest, most effective dose of this medicine to children.

WHERE CAN I LEARN MORE ABOUT THIS CLINICAL TRIAL?

A summary of the results can be found online at pediatrictrials.org. If you have additional questions, please speak with the doctor or staff at your study site.

WHO CONDUCTED THE STUDY?

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 doses of commonly used medicines for infants and children. Children aren't just little adults. Their bodies are growing and changing, meaning that they process medicines differently than adults do. The PTN works to make sure doctors and families have the information they need to give children the right dose: one that will get them well and keep them safe.

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* This summary was completed on [June/2020]. Newer information since this summary was written may now exist. This summary includes only results from one single study. Other studies may find different results.



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