PHARMACOKINETICS OF UNDERSTUDIED DRUGS ADMINISTERED TO CHILDREN PER STANDARD OF CARE (PTN POPS/POP01)

WHY WAS THIS STUDY NEEDED?

Many drugs that physicians prescribe to children are understudied and many lack dosing recommendations. This lack of information on pediatric drug dosing and safety can put children at risk for side effects and treatment failure when given a drug therapy that is not dosed appropriately.

3500 participants under the age of 21

WHAT KIND OF STUDY WAS THIS?

This study was conducted to determine dosing guidelines and recommendations of understudied drugs for children. It was a pharmacokinetic study, which means it looks at how much of the drug gets into the body, where it goes, and how long it takes for the body to get rid of it. The study enrolled approximately 3500 participants under the age of 21, and they participated in the study for up to 90 days.

WHAT WERE THE STUDY RESULTS?

There were multiple DOIs (drug of interest) in this study and each had its own outcomes and results. The results of these studies were submitted to the U.S. Food and Drug Administration (FDA) to change labels of each drug. Five label changes, ampicillin, clindamycin, doxycycline, meropenem, and sulfamethoxazole-trimethoprim (Bactrim), have been accepted by the FDA.

pediatrictrials.org

WHERE CAN I LEARN MORE ABOUT THIS CLINICAL TRIAL?

A summary of the results for this trial can be found 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.

WHAT HAPPENED DURING THE STUDY?

Understudied drugs were administered to children by physicians per routine care, according to their diagnosis and drug therapy needed. Blood samples were taken during each routine physician's visit and a small sample was given to researchers for this study. Researchers determined how much of the drug was absorbed by the participant by measuring the amount of the drug in the bloodstream. Once blood levels are obtained, researchers and clinicians are able to determine the best dosages for each drug.

WHAT SIDE EFFECTS DID THE DRUGS IN THE PTN POPS STUDY HAVE?

There were no side effects or adverse events reported in participants for any of the drugs studied.

WHAT HAPPENS NEXT?

The results of this study were sent to the U.S. Food and Drug Administration (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. This new label gives doctors the information they need to help them give the safest, most effective dose of this medicine to children and teens.

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** This summary was completed in [August 2021].*
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.

PEDIATRIC TRIALS NETWORK

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