Safety of Metronidazole for Infants with Complicated Intra-abdominal Infections

WHY WAS THIS STUDY NEEDED?

Metronidazole is an antibiotic that is often used when treating infants with complicated intra-abdominal infections (cIAIs). However, the medicine is not approved for use in infants by the U.S. Food and Drug Administration (FDA). Additionally, concerns have been raised about how metronidazole interacts with other medicines that may be used in treatment of cIAIs. This study was needed to learn more about the safest and most effective dosage of metronidazole for treating cIAIs in infants.

WHAT KIND OF STUDY WAS THIS?

This summary describes an analysis of infants who were born at 34 weeks gestation or later and given metronidazole to treat cIAIs. The data comes from The Antibiotic Safety in Infants with Complicated Intra-Abdominal Infections (SCAMP) trial. SCAMP tested several antibiotics for safety and effectiveness in treating cIAIs in infants. The data for this study was obtained from 55 infants.

WHAT HAPPENED DURING THE STUDY?

Metronidazole was given to infants at dosages based upon their age. Other treatments, including additional antibiotics, were also used according to how the study site would normally treat cIAIs. Safety of metronidazole was measured by reporting of negative effects.

WHAT WERE THE STUDY RESULTS?

Only one negative side effect, a rash caused by yeast, was possibly associated with metronidazole. Fifty-three infants were treated successfully. Therefore, researchers determined that antibiotic treatment including metronidazole was safe in this group of infants.

WHAT HAPPENED NEXT?

Larger studies are needed to learn safest and most effective dosage of metronidazole for all newborns and infants with cIAIs.

The results of this study were sent to the 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 this medicine to children.

WHERE CAN I LEARN MORE ABOUT THIS CLINICAL TRIAL?

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

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 ways to use medicines and devices in 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 do. The PTN works to make sure doctors and families have the information they need to give children the best care.

The study was made possible with support from the Eunice Kennedy Shriver National Institute of Child Health and Human Development.

** This summary was completed in July 2023. Newer information since this summary was written may now exist. This summary includes only 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