Pharmacokinetics of Rifampin in preterm and term infants

WHY WAS THIS STUDY NEEDED?

Most bloodstream infections in hospitalized infants are caused by Staphylococcus (staph) species including methicillin-resistant Staphylococcus aureus (MRSA). Rifampin is an FDA-approved antibiotic but has not been evaluated for treating staph infection in infants. This summary is from a study performed by the Pediatric Trials Network (PTN). The study was titled "Rifampin Pharmacokinetics and Safety in Preterm and Term Infants." The purpose of the study was to find out the pharmacokinetics and safety of rifampin in infants with suspected infections. Term infants are babies born on time, typically after 37 weeks in the womb. Preterm (or premature) infants are babies born before 37 weeks.

WHAT WERE THE STUDY RESULTS?

Researchers identified doses of rifampin that could treat infants with MRSA. They found that the dose needed was related to how old the infants were in days. They did not observe any significant side effects linked to rifampin.

WHAT HAPPENED NEXT?

PTN submitted the data from this study to the FDA to change the label for rifampin. A medicine's label contains necessary information for health care providers to use when prescribing it. The new label now includes dosage recommendations for infants.

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?

Pharmacokinetic studies see how the human body processes medicines. In this study, researchers checked how the amount of rifampin in the infants' blood changed over time compared to the dose they received. Understanding how infants process rifampin will ensure they receive the right amount to treat MRSA infections.

WHAT HAPPENED DURING THIS STUDY?

A total of 27 preterm and term infants received rifampin as part of either the study or their regular care. The infants were born after 23 to 41 weeks of pregnancy and were between 0 and 84 days old. They gave blood samples to measure the amount of rifampin in their blood. Researchers used these results to see how the infant's bodies process rifampin compared to how adult's bodies process rifampin.

WHO PERFORMED THIS STUDY?

This study was conducted by the 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 from 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 September 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.*

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