Pharmacokinetics of sildenafil in extremely premature infants

WHY WAS THIS STUDY NEEDED?

Infants born too early can get a lung disease called Bronchopulmonary dysplasia (BPD). Infants with BPD are likely to have pulmonary hypertension, a condition where the blood vessels in the lungs get blocked or destroyed, causing high blood pressure. Pulmonary hypertension increases the risk of death from BPD.

There are no medicines approved by the U.S. Food and Drug Administration (FDA) for treating BPD. However, doctors often use the medicine sildenafil to manage high blood pressure in infants with BPD. This study by the Pediatric Trials Network (PTN), called "Pharmacokinetics of Sildenafil in Premature Infants," was needed to learn how premature infants process sildenafil, if it is safe for them, and the best amount they should receive.

Pharmacokinetics is the study of how our bodies process medicines. Understanding pharmacokinetics helps make sure that infants receive the right amounts of medicine.

WHAT KIND OF STUDY WAS THIS?

This study tested how premature infants' bodies process sildenafil. The study also helped researchers learn about the safety of sildenafil for premature infants. Six health care centers across the United States enrolled a total of 34 infants. All were receiving sildenafil.

This was the first study of how premature infants process the medicine sildenafil.

WHAT HAPPENED DURING THIS STUDY?

Infants enrolled in this study received sildenafil either as a liquid fed to them or through a vein. Some infants got just one dose of sildenafil, while others got multiple doses. Researchers tested samples of the infants' blood to see how much sildenafil remained in their bodies over time. Any negative effects related to sildenafil were documented.

WHAT WERE THE STUDY RESULTS?

Researchers developed a formula that can predict how premature infants process sildenafil. This formula will help decide the amount of sildenafil to use in future studies.

There was one negative effect related to sildenafil. One infant got the medicine faster than usual through their vein, resulting in low blood pressure. This taught researchers that sildenafil given too quickly can cause dangerously low blood pressure. There were no other negative side effects related to sildenafil in the study.

WHAT HAPPENS NEXT?

The results informed a follow-up PTN study of the best dosage of sildenafil for treating pulmonary hypertension caused by BPD. Larger studies are needed in the future to learn other side effects and factors that may impact how premature infants process sildenafil. This study was an important first step in testing sildenafil as a treatment for infants with or at risk of pulmonary hypertension from BPD.

WHO PERFORMED 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 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.

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

WHERE CAN I LEARN MORE ABOUT THIS CLINICAL TRIAL?

A summary of the results for this trial, as well as related publications and news, can be found at pediatrictrials.org.

** This summary was completed in July 2024. 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.*

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