

# MEROPENEM IN INFANTS STUDY

## WHY WAS THIS STUDY NEEDED?

Infections in the intestines are common in premature infants younger than three months old. These infections are dangerous, and the infants often die. Meropenem is a medicine used to treat many different kinds of infections. It was approved for use in adults and older children, but until this study no one knew how the medicine affects infants younger than three months old.

## WHAT HAPPENED DURING THE STUDY?

About 200 infants participated in the study at 24 hospitals across the nation. All the infants were given meropenem based on 1) their age and 2) how far along their mothers were in the pregnancy when they were born. Researchers took blood samples from each infant to look at how much of the medicine stayed in their bodies over time. Most of these samples were taken as part of the babies' regular care, so very few extra needle sticks were needed. Also, the samples taken were tiny — about 4 drops of blood!

## WHAT WERE THE STUDY RESULTS?

The study found that meropenem is safe for young infants with infections in their intestines. The dose should be based on:

- Their age
- How far along their mothers were in the pregnancy when they were born

## WHAT HAPPENED 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. The 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.

## WHERE CAN I LEARN MORE ABOUT THIS CLINICAL TRIAL?

A summary of the results for this trial can be found at [pediatrictrials.org](http://pediatrictrials.org). If you have additional questions, please speak with the doctor or staff at your study site.

\* This summary was completed in [July/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.

**BILIRUBIN** is an orange-yellow pigment that occurs normally when part of your red blood cells break down. If your bilirubin levels are high, it may mean that your liver isn't breaking down waste like it should.

**CREATININE** is a waste product that is produced during the normal breakdown of muscle tissues in the body. The level of creatinine in the blood is often used to check how kidneys are working.

## WHAT KIND OF STUDY WAS THIS?

The study was done to figure out the best dose of meropenem for infants younger than three months old. This was a pharmacokinetic study, which means researchers looked 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. Researchers also wanted to find out how safe the drug is for young infants.

## WHAT SIDE EFFECTS DID INFANTS HAVE?

The most common side effects were high levels of bilirubin and creatinine, seizures, rashes, and diarrhea.

## WHO CONDUCTED THE STUDY?

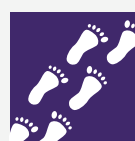
The study was conducted by the Pediatric Trials Network (PTN), a group of more than 100 research sites around the world that are working to find the safest and most effective doses of commonly used medicines for infants and children. Children aren't just little adults. Their bodies are growing and changing, 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.

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

**24**  
HOSPITALS



**~200**  
INFANTS



**PEDIATRIC  
TRIALS NETWORK**

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