

SAFETY AND PHARMACOKINETICS OF LISINAPRIL IN PEDIATRIC KIDNEY TRANSPLANT RECIPIENTS



WHY WAS THIS STUDY NEEDED?

Lisinopril is approved for treating high blood pressure in adults and children over 6 years old. But the best, safest dose of lisinopril in children under age 6 had never been figured out. High blood pressure is common in children and teens who have had a kidney transplant, but no one knew the correct dose for this group either.

WHAT HAPPENED DURING THE STUDY?

The children and adolescents were given lisinopril for high blood pressure after their kidney transplant. The levels of lisinopril were measured in their bodies over time, which helped researchers figure out the best dose for this group.



28

CHILDREN
2-17 YEARS OLD

WHAT WERE THE STUDY RESULTS?

The study found that children do not process lisinopril differently based on their age or whether or not they have a kidney transplant. The suggested dose of lisinopril for adults and children over age 6 with high blood pressure should be the same for children who have had a kidney transplant.

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. 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.

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.

WHAT KIND OF STUDY WAS THIS?

The study was done to find the best dose of lisinopril to treat high blood pressure in children who have received a kidney transplant. 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 28 pediatric patients ranging from 2-17 years old who were doing well after their kidney transplant but who needed medicine to control their high blood pressure. Each child participated in the study for up to 51 days, including 30 days of safety monitoring after they took the medicine.

WHAT SIDE EFFECTS DID CHILDREN AND TEENS HAVE?

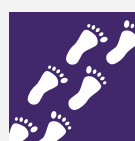
None of the children or teens had any serious side effects from taking the medicine. There was no change in the function of the kidney transplant. Some side effects that may have been because of the medicine included dizziness, nausea, and stomach ache.

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.

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* This summary was completed in [June/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.



**PEDIATRIC
TRIALS NETWORK**

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