Fluconazole for prevention and treatment of yeast infections in infants

WHY WERE THESE STUDIES NEEDED?

Fluconazole is an antifungal medicine often used to treat and prevent yeast infections in infants born prematurely and full-term. In infants, yeast can cause serious infections all throughout the body, including the skin, blood, heart, eyes, and brain. These yeast infections occur because infants have weaker immune systems than older children and adults, and the infections can lead to long-term health issues or even death. Despite the frequent use of fluconazole in infants, there was little data available on the pharmacokinetics, or how the medicine is processed in infants' bodies. There was also little data on the safety and effectiveness of fluconazole for infants. These studies were needed to identify how fluconazole is processed, its safety and effectiveness, and the best dosage for treating and preventing yeast infections in premature and full-term infants, as well as infants using life support.

WHAT HAPPENED DURING THE STUDIES?

Infants received fluconazole, and samples of their body fluids were tested to see whether the infants developed a yeast infection, as well as how long it took their bodies to process fluconazole. Any negative outcomes related to fluconazole treatment were documented. In one study, researchers checked in on participants when they were 18-22 months old to find out if there were any effects on their brain development.

WHAT HAPPENED NEXT?

The data from these studies were submitted to the U.S. Food and Drug Administration (FDA) to update the label for fluconazole. The label contains necessary information for health care providers to use when prescribing fluconazole to patients. The new label contains information on pharmacokinetics and dosing suggestions, as well as safety and effectiveness of fluconazole for both treatment and prevention of yeast infections in full-term and premature infants.

Additions to the fluconazole label include:

- Data on how infants' bodies process fluconazole
- Suggestion to use a loading dose of fluconazole for children
- Information on dosing fluconazole for children on life support
- Information on the use of fluconazole for prevention of yeast infections in premature infants

WHAT WERE THE STUDY RESULTS?

Fluconazole was not associated with reducing deaths, but it was associated with reducing yeast infections in infants. The larger dose of fluconazole at the start of treatment helped achieve the most effective amount of fluconazole in the infants' bodies. An even larger loading dose may be required in special circumstances, such as infants on life support, or infants with weakened immune systems. There were no significant effects on infants' brain development.

Researchers created a formula that can accurately predict how an infant may process fluconazole. Researchers recommend that only NICUs or PICUs where yeast infections occur frequently use fluconazole as part of their routine for preventing yeast infections.

WHAT KINDS OF STUDIES WERE THESE?

This summary includes information from four studies on the pharmacokinetics of fluconazole in infants. These studies were supported by The Pediatric Trials Network (PTN). The four studies are:

- Fluconazole Prophylaxis for the Prevention of Candidiasis in Infants <750 Grams Birth Weight
- Safety and Efficacy of Fluconazole Prophylaxis in Infants
- Pharmacokinetics of a Fluconazole Loading Dose in Infants and Toddlers
- Safety and Pharmacokinetics of Fluconazole in Children Supported by Extracorporeal Membrane Oxygenation (ECMO)

These studies evaluated the safety and effectiveness of fluconazole for prevention and treatment of yeast infections in infants who were born prematurely or full-term. Infants being supported by a life support machine were also studied. In total, the studies enrolled 436 infants across more than 30 neonatal intensive care units (NICUs) and pediatric intensive care units (PICUs) in the United States.

Researchers also sought to develop a formula that can predict how infants may process fluconazole, as well as make recommendations about a fluconazole loading dose for infants. A loading dose is a higher dose of medicine given at the beginning of treatment. They're commonly used when giving fluconazole to adults, and they are useful for medicines that the body processes slowly, like fluconazole.

WHO CONDUCTED THE STUDIES?

The studies were supported and submitted to the FDA 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 THESE CLINICAL TRIALS?

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 April 2024. Newer information since this summary was written may now exist. This summary includes only results from four PTN studies. Other studies may find different results.*

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