

Anti-fungal drug not tied to most birth defects, study says

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But experts may still avoid prescribing fluconazole for pregnant women since it's still linked to a rare heart defect.

(HealthDay)—Although some reports have shown that high doses of the anti-fungal drug fluconazole (Diflucan) may raise the risk of birth defects, a new Danish review finds that more commonly prescribed lower doses of the medicine do not carry the same dangers.

Yet, in spite of this reassurance, experts may remain reluctant to prescribe the drug for expectant mothers who have <u>yeast infections</u>, since it is still linked to an increased risk of a rare congenital heart problem called tetralogy of Fallot.

"Many pregnant women suffer from a yeast infection called vaginal candidiasis, or vaginal thrush, which is the most common clinical



indication for use of oral <u>fluconazole</u>," explained lead researcher Ditte Molgaard-Nielsen, an epidemiologist at the Statens Serum Institute in Copenhagen.

First-line treatment for vaginal candidiasis during pregnancy is vaginal preparations of topical anti-fungal drugs, she noted.

"However, in cases when topical treatment is ineffective this study provides comprehensive safety information, and may help inform <u>clinical decisions</u> when treatment with oral fluconazole is considered in pregnancy," Molgaard-Nielsen said.

Specifically, the researchers looked at 15 <u>birth defects</u> linked to fluconazole and found it was not associated with an increased risk for 14 of them, she said.

"However, we did see an increase in the risk of tetralogy of Fallot, an uncommon congenital heart defect, but the number of exposed cases were few and this association should be confirmed in other studies before anything can be concluded with any certainty," Molgaard-Nielsen added.

The report was published Aug. 29 in the *New England Journal of Medicine*.

Dr. Scott Berns, senior vice president and deputy medical officer for the March of Dimes, said that "when pregnant it is important to avoid taking any medicines unnecessarily."

"I would chose the topical drug to treat a yeast infection. That is my first line," he said. "If I had to use oral fluconazole, this study is reassuring that most of the time the baby is going to be fine. But, there is that small chance of tetralogy of Fallot. So, why take that chance?"



Another expert doesn't think these findings will change clinical practice.

"Ob/Gyns are still going to be reluctant to prescribe this drug," said Dr. Kecia Gaither, director of maternal fetal medicine at Brookdale University Hospital and Medical Center in Brooklyn, N.Y.

Gaither prefers to use natural methods for treating yeast infections. "One of them is increasing the use of yogurt intake," she said. "There is certain bacteria in yogurt that prevents yeast infections. I have not run into a person who continues to have recurrent yeast infections after that is done."

For the study, Molgaard-Nielsen's team collected data on more than 7,300 women who took fluconazole during their pregnancy, among whom 210 infants were born with birth defects, and compared them to a control group of more than 968,000 unexposed women, among whom more than 25,000 babies were born with birth defects.

In both groups, the risk for having an infant with a birth defect was 0.6 percent, the researchers found.

Moreover, fluconazole wasn't linked to a significantly increased risk for 14 of 15 birth defects to which the drug had been previously linked, they added.

These include craniosynostosis (a defect in the baby's skull), middle ear defects, cleft palate, cleft lip, limb defects, an abnormal number of finger or toes, fused fingers or toes, diaphragmatic hernia, heart defects and shifting of a lung.

There was, however, a significantly increased risk of tetralogy of Fallot, with seven cases (0.10 percent) among women who took fluconazole, compared with 287 cases (0.03 percent) in unexposed women, the



researchers found.

According to the U.S. National Institutes of Health, tetralogy of Fallot is a rare, complex birth defect where four different areas of the heart are malformed and the heart cannot pump enough blood or oxygen to the rest of the body. Surgery is usually required shortly after birth, although the long-term outlook for these patients has improved greatly in recent years.

More information: For more on vaginal candidiasis, visit the <u>U.S.</u> <u>Centers for Disease Control and Prevention</u>.

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