Study examines effects of taking ondansetron during first trimester of pregnancy

December 18 2018

Credit: CC0 Public Domain

Ondansetron (Zofran) is commonly and increasingly prescribed during pregnancy to relieve nausea. In 2014, an estimated 22 percent of pregnant women in the U.S. had used the drug at some point during their

pregnancy. Despite its prevalence, data on the safety of the drug and any effects on the developing fetus have been limited, with small-scale studies producing conflicting results. A new study conducted by investigators at Brigham and Women's Hospital has analyzed data from more than 88,000 pregnancies in which pregnant women had taken ondansetron during the first trimester to examine risk of cardiac malformations or oral clefts. In a paper published online in *JAMA*, the team reports no increased risk of cardiac malformations and a very small increased risk of oral clefts.

"Use of ondansetron has increased over time, but only a handful of studies had been conducted to date and all were relatively small. We wanted to provide more robust information on two important outcomes—risk of oral clefts and cardiac malformations—for patients and clinicians," said corresponding author Krista Huybrechts, MS, Ph.D., epidemiologist in the Division of Pharmacoepidemiology and Pharmacoeconomics at the Brigham. "Our study expands the evidence available to date and represents the largest published study of tens of thousands of women and fetal outcomes with careful control for potential confounding variables."

Huybrechts and colleagues conducted a retrospective cohort study based on data from the nationwide Medicaid Analytic eXtract (MAX), a dataset that included more than 1.8 million pregnancies resulting in live births between 2000 and 2013 among publicly insured pregnant women. Records showed that patients had filled prescriptions for ondansetron in the first trimester of 88,467 (4.9 percent) pregnancies.

The team found an adjusted relative risk for cardiac malformations of 0.99 with tight confidence intervals (0.93—1.06)—strong evidence of no difference in risk for cardiac malformations between the group exposed to ondansetron and the control group. The researchers report a rate of 94.4 cardiac malformations per 10,000 births among ondansetron-

exposed pregnancies compared to 84.4 per 10,000 among unexposed pregnancies.

The researchers found an increase in oral clefts, but this association was less precisely estimated (confidence interval 1.03—1.48). The researchers found an absolute risk of 14.0 cases per 10,000 births among ondansetron-exposed pregnancies compared to 11.1 cases per 10,000 births in unexposed ones. The team also examined information on congenital malformations overall, finding no increased risk among fetuses exposed to the drug during the first trimester.

"These results suggest that ondansetron does not meaningfully increase the risk of congenital malformations, although a small increase in the risk of oral clefts cannot be excluded," said Huybrechts. "These results will hopefully provide reassurance to pregnant women who experience nausea and vomiting in pregnancy and need to make a risk-benefit trade-off regarding treatment."

Provided by Brigham and Women's Hospital

Citation: Study examines effects of taking ondansetron during first trimester of pregnancy (2018, December 18) retrieved 16 April 2024 from https://medicalxpress.com/news/2018-12-effects-ondansetron-trimester-pregnancy.html

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.