DSEN ABSTRACT

Ondansetron use during pregnancy: Utilization and adverse outcomes (Q16-08)

A study conducted by the Canadian Network for Observational Drug Effect Studies (CNODES)

Summary

- In this large study of 4,103,695 pregnancies, ondansetron use during pregnancy was not associated with increased risks of fetal death, spontaneous abortion, stillbirth, or major congenital malformation, when compared with other commonly used antiemetic drugs.

Key messages

- In this large, international, multi-center retrospective cohort study, pregnant women who use ondansetron do not appear to face increased risks of adverse fetal outcomes compared with pregnant women who use other antiemetics.

Project Lead & Team

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Link to publication

- Dormuth et al. JAMA Netw Op. 2021. doi: 10.1001/jamanetworkopen.2021.5329.

What is the issue?

- Ondansetron is frequently used off-label for the treatment of nausea and vomiting during pregnancy.
- Most studies to date were not sufficiently large to consider rarer outcomes such as major birth defects and defect subtypes with use of this medication.
- Canadian data on the use of ondansetron during pregnancy are limited.

What was the aim of the study?

- CNODES evaluated the use of ondansetron during pregnancy and its association with major congenital malformations, as compared with other antiemetics.

How was the study conducted?

- We undertook a retrospective cohort study using administrative health databases with 4,103,695 pregnancy episodes from 5 Canadian provinces (British Columbia, Alberta, Saskatchewan, Manitoba and Ontario), as well as the US IBM MarketScan® database, and the UK Clinical Practice Research Datalink.
- Exposure to ondansetron was compared with exposure to other antiemetic drugs. The primary outcome was fetal death (composite of spontaneous abortion or stillbirth) and the secondary outcomes were separate analyses of spontaneous abortion, stillbirth and major congenital malformations.
- Hazard ratios (HR) were estimated for fetal death, spontaneous abortion, and stillbirth using Cox proportional hazards models. The adjusted odd ratio (OR) was estimated for major congenital malformations using logistic regression.
- Sensitivity analyses were conducted with second-line antiemetic exposure and exposure occurring specifically during 4 to 10 weeks of gestation.

What did the study find?

- During pregnancy, 4.5% of women were exposed to ondansetron and 11.4% for other antiemetic drugs. Antiemetic use was similar in the US (16%) and Canada (20%) but was less in the UK (4%). In Canada and the UK, 3% of antiemetic exposures involved ondansetron compared to 59% in the US.
- Fetal death occurred in 7.9% of the 163,810 pregnancies exposed to ondansetron and in 5.7% of 306,766 pregnancies exposed to other antiemetic drugs.
- Ondansetron use was not associated with an increased risk of fetal death (HR 0.91, 95% confidence interval [CI] 0.67-1.23), spontaneous abortion (HR 0.82, 95% CI 0.64-1.04), stillbirth (HR 0.97, 95% CI 0.79-1.20), or major congenital malformations (odds ratio [OR] 1.06, 95% CI 0.91-1.22), compared with other antiemetic drugs.
- The findings were generally consistent across various sensitivity and subgroup analyses.

This research was funded by CIHR – Drug Safety and Effectiveness Network and conducted by CNODES:

CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

CNODES CANADIAN NETWORK FOR OBSERVATIONAL DRUG EFFECT STUDIES

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