

Medication taken for nausea during pregnancy not associated with increased risk of major malformations

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In an analysis that included more than 40,000 women exposed to the nausea medication metoclopramide in pregnancy, use of this drug was not associated with significantly increased risk of major congenital malformations overall, spontaneous abortion, and stillbirth, according to a study in the October 16 issue of *JAMA*.

More than 50 percent of pregnant women experience nausea and vomiting, typically early in their [pregnancy](#). The care of most women is managed conservatively, but 10 percent to 15 percent of those with nausea and vomiting will eventually receive drug treatment. Metoclopramide is often recommended if treatment with an antihistamine or vitamin B6 has failed. Despite [metoclopramide](#) being one of the most commonly used prescription medications in pregnancy, data on the safety of its use in pregnancy are limited, according to background information in the article.

Bjorn Pasternak, M.D., Ph.D., of the Statens Serum Institut, Copenhagen, and colleagues conducted a study to investigate associations between metoclopramide use in pregnancy and serious adverse outcomes. The study included 1,222,503 pregnancies in Denmark from 1997-2011 and compared outcomes for women who used metoclopramide to those who did not.

In a group that included [women](#) exposed and unexposed (control group)

to metoclopramide, there were 28,486 live-born infants exposed to metoclopramide in the first trimester of pregnancy and 113,698 unexposed infants. Of these, 721 exposed (25.3 per 1,000 births) and 3,024 unexposed infants (26.6 per 1,000 births) were diagnosed with any major malformation during the first year of life. In analyses of individual malformation categories, there were no associations between metoclopramide use in the first trimester and any of the 20 malformations, including neural tube defects, cleft lip, cleft palate and limb reduction.

The researchers also observed no increased risk of [spontaneous abortion](#), stillbirth, preterm birth, [low birth weight](#), and [fetal growth restriction](#) associated with metoclopramide use in pregnancy.

"These safety data may help inform decision making when treatment with metoclopramide is considered in pregnancy," the authors conclude.

More information: [DOI: 10.1001/jama.2013.278343](https://doi.org/10.1001/jama.2013.278343)

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