

No risks to pregnancy seen with morning sickness drug

February 27 2013, by Amy Norton, Healthday Reporter



Large Danish study of ondansetron found no rise in miscarriage, birth defects.

(HealthDay)—A drug commonly used to treat severe cases of morning sickness does not appear to be linked to birth defects or other risks to the baby, a large new study suggests.

The Danish researchers said the findings, reported in the Feb. 28 issue of the [New England Journal of Medicine](#), do not prove the medication is risk-free. But they said the study should reassure [women](#) who need the drug, called ondansetron ([Zofran](#) and generics).

"We can never say it's 100 percent safe," said Christina Chambers, co-director of the Center for Promotion of [Maternal Health](#) and Infant Development at the University of California, San Diego.

"But this is a good study that really adds to what we've known," said Chambers, who was not involved in the work.

The findings are based on records from more than 600,000 Danish women who were pregnant between 2004 and 2011. Of those women, about 0.3 percent received prescriptions for ondansetron. About half had nausea and vomiting severe enough that they had been hospitalized.

Overall, there was no evidence that the medication increased the risks of miscarriage, stillbirth, preterm delivery or major birth defects, according to the researchers, led by Dr. Bjorn Pasternak of the Statens Serum Institute in Copenhagen.

Of women given the morning-sickness drug in the [first trimester](#), for example, just over 1 percent had a miscarriage, versus almost 4 percent of women who did not take the medication. And in both groups, 3 percent of moms had a baby with a major [birth defect](#), such as a heart defect or malformations of the brain or spine, including spina bifida.

The study, which was funded by the Danish Medical Research Council, has its limits, Chambers said. It is observational, meaning it relied on women's medical records and looked for correlations between ondansetron prescriptions and risks to the developing fetus.

That's not enough to prove no risks exist, Chambers noted.

The researchers did account for other factors in a healthy pregnancy, such as the women's age and income and whether they smoked. But they couldn't factor in everything that affects pregnancy outcomes, Chambers said.

Dr. Jennifer Wu, an obstetrician/gynecologist at Lenox Hill Hospital in New York City, agreed. "It's an observational study, but that's what we

have to go on," she said.

The best kinds of studies for showing a drug's benefits and risks are controlled clinical trials, where patients are randomly assigned to take a medication or not. It is generally considered unethical to include pregnant women in such studies, however, so doctors have to rely on studies like the current one—records-based studies that look at whether pregnant women who used a given medication show any increased risks.

That's not ideal, but the new findings are reassuring, Wu said.

"This is a drug we've been using for a while," she said. "It can help keep women out of the hospital, and help keep them functioning on a day-to-day basis." For some women, Wu said, nausea and vomiting can be so severe that they can't get out of bed.

It's estimated that more than half of all [pregnant women](#) suffer from morning sickness. Usually, women can manage it without medication by, for example, eating smaller meals throughout the day, avoiding spicy foods and steering clear of strong smells that nauseate them.

But for some women, the problem is debilitating, and a small percentage develop hyperemesis, where a woman cannot keep any food down and she begins to lose weight.

[Ondansetron](#) fights nausea by lowering activity in the hormone serotonin. In the United States, it's the most commonly prescribed anti-nausea drug, and it is officially approved to treat nausea from cancer chemotherapy, radiation therapy and surgery. Its use against morning sickness has been based on only limited safety data.

"This study is reassuring in that it's a large database," Chambers said. "It supports this as an option for women."

The drug can have side effects for expectant moms. This study did not look at that, but in general the most common ones include constipation, dizziness, fatigue and headache.

According to the American College of Obstetricians and Gynecologists, some other options for severe [morning sickness](#) include vitamin B6, possibly along with a [drug](#) called doxylamine, which is found in over-the-counter sleep aids.

More information: Learn more about [morning sickness](#) from the American Pregnancy Association.

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