

Use of certain antiviral drugs during pregnancy not linked with higher risk of major birth defects

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An analysis of data from Denmark finds no associated increased risk of major birth defects for mothers who were exposed during the first trimester of pregnancy to the antiviral drugs acyclovir, valacyclovir, and famciclovir, often used to treat herpes simplex and herpes zoster infections, according to a study in the August 25 issue of *JAMA*.

The prevalence of herpes simplex is high, and more than 1 percent of susceptible women acquire herpes simplex during the first trimester of pregnancy, with [antiviral treatment](#) indicated for a significant number of women in pregnancy. "Although the safety of acyclovir, valacyclovir, and famciclovir in general has been well established, data on the use of these antivirals in [early pregnancy](#) are limited," the authors write.

Bjorn Pasternak, M.D., Ph.D., and Anders Hviid, M.Sc., Dr.Med.Sci., of Statens Serum Institut, Copenhagen, Denmark, conducted a registry-based study to assess associations between acyclovir, valacyclovir, and famciclovir use in the first trimester of pregnancy and major birth defects. The study included 837,795 live-born infants in Denmark from January 1996 to September 2008. Participants had no diagnoses of chromosomal aberrations, genetic syndromes, birth defect syndromes with known causes, or congenital viral infections. Nationwide registries were used to ascertain individual-level information on dispensed antiviral drugs, birth defect diagnoses and potential confounders (factors that can influence outcomes).

Among 1,804 pregnancies exposed to acyclovir, valacyclovir, or famciclovir at any time in the first trimester, 40 infants (2.2 percent) had a diagnosis of a major birth defect, compared with 19,920 of 835,991 infants (2.4 percent) among the unexposed pregnancies. Adjusting for several variables, acyclovir, valacyclovir, or famciclovir exposure at any time in the first trimester was not associated with increased risk of major birth defects. First-trimester use of acyclovir, the most commonly prescribed antiviral, was not associated with major birth defects (32 cases among 1,561 exposed [2.0 percent] vs. 2.4 percent in the unexposed). Neither valacyclovir (7 of 229 infants [3.1 percent]) nor famciclovir (1 of 26 infants [3.8 percent]) were associated with major birth defects, although use of famciclovir was uncommon.

Additional analyses revealed no associations between antiviral drug exposure and 13 different subgroups of birth defects, but the number of exposed cases in each subgroup was small.

"Our study, to our knowledge the largest of its kind, found no significant association between first-trimester exposure to antiherpetic [antiviral drugs](#) and major [birth defects](#). Consequently, it has immediate clinical implications and may support informed decisions on safety when prescribing antivirals for [herpes](#) infections in early pregnancy. Acyclovir is the most extensively documented antiviral and should therefore be the drug of choice in early pregnancy, while data on valacyclovir and famciclovir are still insufficient. Future research on antiherpetic antivirals and mother-child health should include safety studies with regard to spontaneous abortion and preterm birth, and during breastfeeding," the authors conclude.

More information: *JAMA*. 2010;304[8]:859-866.

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