U.S. Study Confirms Low Rate of Birth Defects Among Women With HIV

Findings suggest exposure to antiretrovirals, including dolutegravir, during pregnancy does not raise the risk of neural tube defects.

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Women with HIV in the United States are no more likely than those in the general population to give birth to infants with neural tube birth defects, according to a recent study from the Centers for Disease Control and Prevention (CDC).

Although this analysis was not able to assess the use of specific antiretroviral drugs during pregnancy, the findings suggest that HIV medications—including dolutegravir—do not raise the risk of these birth defects.

Dolutegravir (Tivicay, also a component of the Triumeq, Juluca and Dovato combination pills) is well tolerated and highly effective and a preferred component of antiretroviral treatment for adults according to U.S. and international guidelines.

Concerns about the use of dolutegravir during early pregnancy arose in 2018, when early results from a surveillance study in Botswana revealed a higher than expected rate of neural tube defects among infants exposed to the drug near the time of conception. These birth defects, including spina bifida and anencephaly, involve incomplete development of the brain or spinal cord. They typically arise during the first several weeks of gestation, often before a woman realizes she's pregnant.

Interim results from the Tsepamo study showed that the risk of neural tube defects in infants born to mothers who took dolutegravir around the time of conception was 0.94%, or four cases out of 426 pregnancies. This compares with a rate of 0.12% among HIV-positive women who took other antiretrovirals and 0.09% among HIV-negative women. However, updated findings showed only a single additional case among 1,275 additional women who used dolutegravir around conception, lowering the cumulative rate to 0.30%.

These concerns prompted CDC researchers to assess rates of birth defects among infants born to HIV-positive women in the United States. To do so, they used data from state birth defect surveillance programs (which do not collect HIV status) as well as state HIV surveillance programs (which do not routinely collect data on birth defects).

Data from these programs were linked to estimate the prevalence of neural tube defects overall and among pregnancies of women with HIV from 2013 through 2017—the five years after dolutegravir was approved. However, associations between specific antiretrovirals and birth defects could not be assessed because information about maternal use of antiretroviral therapy is not routinely collected, the researchers noted.

As reported in a recent Morbidity and Mortality Weekly Report, the CDC team contacted the 20 jurisdictions with the highest numbers of HIV-positive women of reproductive age that also had birth defect surveillance programs. Fifteen jurisdictions were able to perform the data linkage: 11 states, the Atlanta metropolitan area, New York City, Philadelphia and Puerto Rico.

Altogether, the participating jurisdictions had surveillance data for 64,272 women with HIV ages 13 to 44, representing about 70% of all HIV-positive women of childbearing age in the United States in 2015. These jurisdictions also had information about more than 8 million live births during 2013 to 2017. Data linkage identified 11,425 live births to women with HIV during this period.

Eight cases of neural tube defects were identified in the HIV-positive group, for a prevalence of 7.0 per 10,000 live births, or 0.07%. This was similar to the rate of 5.8 cases per 10,000 live births in the general population, or 0.06%.

“Because data on pregnancy and ongoing antiretroviral medication use are not routinely collected in many state HIV surveillance programs, and HIV treatment options are evolving, continued efforts to collect information on pregnancies affected by maternal HIV infection are needed to understand the association between HIV treatment and birth defects and other pregnancy outcomes,” the authors concluded.

Current Recommendations

After the interim findings from the Tsepamo study were reported, the World Health Organization (WHO) advised that HIV-positive women of childbearing age should not use dolutegravir unless they had consistent access to reliable contraception. Likewise, the U.S. Department of Health and Human Services (HHS) antiretroviral therapy guidelines recommended against the use of dolutegravir during the first 12 weeks of pregnancy or by people of childbearing potential who are planning to become pregnant or are sexually active and not using effective contraception.

Following the release of the updated Botswana results last summer, the WHO issued revised guidelines recommending dolutegravir as the preferred option for first-line treatment for adults and adolescents, including pregnant women and those who could become pregnant.

The latest update to the HHS antiretroviral guidelines, released in December, recommends that HIV-positive people of childbearing potential and their providers should discuss the benefits of using dolutegravir and the risk of neural tube defects so they can make informed decisions.

These guidelines now include dolutegravir as a recommended option for people using effective contraception and an alternative drug for those who are trying to conceive or are sexually active and not using contraception. The latest HHS perinatal guidelines list dolutegravir as a preferred antiretroviral drug throughout pregnancy.

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