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Opinion Article

Pharmacokinetics: Dolutegravir in HIV-Positive Pregnant Women

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DESCRIPTION

Dolutegravir (DTG), an integrase strand transfer inhibitor, is being introduced as an alternative to first-line treatment with non-nucleoside reverse transcriptase inhibitors in Low and Middle-Income Countries (LMICs). DTG, on the other hand, is not widely recommended for use in pregnant women. The goal of this analytical study was to examine all available data on birth outcomes and congenital anomalies in DTG-treated pregnant women's infants. DTG generic versions are already available as a single table regimen. A generic fixed-dose combination of tenofovir, lamivudine, and dolutegravir (TDF/3TC/DTG) is now available at a median per individual in some Low- and Middle-Income Countries (LMICs), making a DTG-containing regimen more affordable than first-line EFV-containing regimens.

Before widely introducing DTG into national treatment programmes in LMICs, where women of childbearing age make up a large proportion of the HIV-positive population, the risks of adverse birth outcomes with in utero DTG exposure should be assessed. DTG studies revealed no infertility or foetal harm, even at high doses. *Ex vivo* studies show that DTG crosses the placenta, and two studies of infants exposed to DTG in utero have revealed cord blood drug concentrations higher than maternal plasma concentrations, indicating significant foetal exposure. When the benefits outweigh the risks, DTG is indicated for use during pregnancy. Due to the reduced stability and effectiveness data available in pregnant women, the WHO currently lists DTG as an alternative, rather than a preferred option, for first-line HIV treatment. The Department of Health and Human Services (DHHS) had enough data to recommend routine use of DTG-containing regimens for antiretroviral-naive pregnant women as an alternative agent for antiretroviral-naive women. Botswana is the only LMIC where DTG is commonly used in pregnant women. A study is currently underway to assess birth outcomes and congenital anomalies in the infants of pregnant women treated with DTG as part of a larger study to assess the safety of antiretroviral in pregnancy. There are observational studies and research projects underway in North America and Europe where women take DTG during pregnancy to evaluate birth outcomes, congenital anomalies, and pharmacokinetics.

Our findings suggest that patients with HIV receiving dolutegravir-based antiretroviral therapy can receive 12 once-weekly doses of rifapentine-isoniazid for tuberculosis prophylaxis with no dose adjustments. More study into the pharmacokinetics, safety, and efficacy in children, as well as the pharmacodynamics in people new to antiretroviral therapy, is required. The purpose of this systematic study was to determine the prevalence of specific pregnancy outcomes and birth defects, as well as the pharmacokinetics of DTG in pregnant women living with HIV. Women were advised to use contraception during the original DTG clinical trials programme, and any women who became pregnant were removed from DTG treatment. Although these measures are common in early clinical development studies, they have resulted in a scarcity of data on treatment outcomes in pregnant women.

As a result, because randomized trials have yet to be completed, non-randomized observational studies are the primary source of information on DTG in pregnancy. The APR is a voluntary reporting system that includes only a subset of birth outcomes at the national level and does not include all births with first-trimester DTG exposure. The APR data included 142 women (140 HIV positive and two HIV negative) who reported using DTG during pregnancy. The women were mostly from treatment facilities in states. Data was gathered prospectively. Stillbirths, spontaneous abortions, SGA, and low birth weight were all considered adverse pregnancy outcomes. Only new cases in this cohort had congenital anomalies.

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