Study Backs Up WHO's Policy on Dolutegravir for Pregnant Women With HIV

The study randomized women starting HIV treatment during their third trimester to dolutegravir- or efavirenz-based antiretroviral regimens.

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A new study has affirmed the revised guidelines from the World Health Organization (WHO) recommending that HIV care providers transition to prescribing dolutegravir for first-line antiretroviral (ARV) treatment for all adults, regardless of pregnancy status or the child-bearing potential of women living with the virus.

In 2018, a study in Botswana raised concerns that exposure to dolutegravir (Tivicay, also a component of the Triumeq, Juluca and Dovato combination pills) during early gestation might increase the risk of neural tube birth defects. Follow-up data, however, showed that the occurrence of birth defects was very low and similar to the rate seen in the general population.

A global team of researchers published findings from the randomized, open-label DolPHIN-2 trial in The Lancet HIV. The study recruited pregnant women in South Africa and Uganda with untreated HIV who were an estimated 28 weeks into their pregnancy. The women were all starting ARVs for the first time in their third trimester.

Between January 23 and August 15, 2018, the investigators randomly assigned 268 expectant mothers to receive a dolutegravir-based (135 women) or an efavirenz-based (133 women) ARV regimen.

The investigators measured the women's viral load seven and 28 days after they started ARVs, at 36 weeks' gestation and at the postpartum medical visit, which took place within 14 days of their giving birth. All the mothers and their infants were included in the study's safety analyses.

The median duration of ARV treatment by the time the women delivered their infants was 55 days. Eighty-nine (74%) of the members of the dolutegravir group had a viral load below 50 at delivery, compared with 50 (43%) in the efavirenz group. This meant that receiving dolutegravir was associated with a 1.64-fold greater likelihood of having an undetectable viral load at delivery.

Thirty (22%) of the mothers in the dolutegravir group reported experiencing serious adverse health events, compared with 14 (11%) of those in the efavirenz group, particularly surrounding pregnancy and the approximate six-week period following delivery during which internal organs shift back to their prepregnancy positions.

The study authors found no differences in the rate of preterm births that took place before 37 weeks of gestation and before 34 weeks of gestation—16.4% and 3.3%, respectively, in both the dolutegravir and efavirenz groups.

There were three stillbirths in the dolutegravir group and one in the efavirenz group; all were considered unrelated to HIV treatment.

Three infants—all born to mothers in the dolutegravir group—tested positive for HIV. They are believed to have likely contracted the virus in utero.

“Our data support the revision of the WHO guidelines recommending the transition to dolutegravir in first-line [ARV treatment] for all adults, regardless of pregnancy or child-bearing potential,” the study authors concluded.

To read a press release about the study, click here.

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