Tivicay Bests Sustiva for Women Starting HIV Treatment Late in Pregnancy

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Among a group of sub-Saharan African women who started HIV treatment late in their pregnancies, Tivicay (dolutegravir) was more effective than Sustiva (efavirenz) at fully suppressing the virus by the time of delivery, the National AIDS Treatment Advocacy Project (NATAP) reports. Having an undetectable viral load at delivery lowers the risk of mother-to-child transmission of HIV.

Presenting their findings at the 2019 Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle, researchers from the DOLPHIN-2 study assessed Tivicay and Sustiva's effectiveness among pregnant women in Uganda and South Africa. The women were not on ARVs and started treatment through the trial after they had passed 28 weeks of gestation.

The participants could not have: taken ARVs within 12 months of entering the study, taken an integrase inhibitor previously or experienced previous failure on a non-nucleoside reverse transcriptase inhibitor (NNRTI) or intolerance of Sustiva.

A total of 256 pregnant women were randomized to receive two NNRTIs plus either Tivicay or Sustiva. The study's analysis included 249 participants: 126 women took Tivicay, and 123 women took Sustiva.

The women had similar characteristics at the study's outset. They had a median age of 28 and a median estimated gestation of 31 weeks, had given birth to a median of two live children and had a median CD4 count of 446.

At delivery, 73.8 percent of the women who received Tivicay had a fully suppressed viral load, compared with 42.6 percent of those who received Sustiva. Among the 198 women who started the study with a viral load below 100,000, a respective 78.9 percent and 48.9 percent of the women in the Tivicay and Sustiva groups had a fully suppressed viral load. Viral suppression rates among the 206 women who started the trial with a CD4 count above 200 were 75.9 percent in the Tivicay group and 45.9 percent in the Sustiva group. The rates among the 200 women who started treatment before 36 weeks of gestation were a respective 74.5 percent and 44.1 percent in the Tivicay and Sustiva groups.

Starting Tivicay as opposed to Sustiva raised the likelihood of viral suppression at delivery 1.66-fold. Adjusting the data to account for differences between the women in their baseline viral load, their gestation week upon enrolling in the study, as well as age and country, did not alter the finding of Tivicay's superior performance.

The women in the Tivicay group had higher viral suppression rates at delivery compared with those in the Sustiva group in the following subgroups: the 39 women who started the study with a viral load greater than 100,000; the 31 women who had an initial CD4 count below 200; and the 37 women who started treatment at week 36 of gestation or later. However, these differences were not statistically significant, likely in part because of the small size of the subgroups.

Women in the Tivicay group had been on ARV treatment for a median 52 days at delivery, compared with 59 days in the Sustiva group.

Three women from the Tivicay group transmitted HIV to their infants. Researchers believe the infants contracted the virus in utero.

Two women (1.5 percent) in the Tivicay group and five (3.8 percent) in the Sustiva arm had at least one drug-related serious adverse health event. One woman (0.7 percent) in the Tivicay group and two women (1.5 percent) in the Sustiva group had a serious adverse health event related to a case of immune reconstitution inflammatory syndrome (IRIS). A serious and potentially fatal condition, IRIS may arise after people with HIV start ARVs, in particular if they have a low CD4 count and a high viral load.

Among the infants, 52.8 percent in the Tivicay group and 46.2 percent in the Sustiva group experienced serious adverse health events.

Four (2.9 percent) of the women in the Tivicay arm experienced stillbirths, which the investigators deemed unlikely to be related to HIV treatment. During the study's follow-up period, five (4.1 percent) infants in the Tivicay group and three (2.5 percent) in the Sustiva group died.

The researchers indicated that the deaths, stillbirths and infections seen among the infants were a reflection of the poor health outcomes previously reported about this group of women.

To read the conference abstract, click here.

To view a webcast of the conference presentation, click here.

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