Rate of Tivicay's Central Nervous System Side Effects Is Greater Than in Trials

The HIV drug is associated with a high rate of insomnia, dizziness and headache, especially among women and those over 60.

December 13, 2016

Tivicay (dolutegravir) is associated with a higher rate of central nervous system side effects than was seen in clinical trials of the antiretroviral, aidsmap reports.

The risk of side effects such as insomnia, dizziness and headache is greater among women, people age 60 and older and those who start Ziagen (abacavir) at the same time as Tivicay.

Tivicay is a second-generation integrase inhibitor and a recommended first-line treatment for HIV. It was approved in the United States in 2013. Phase IIb and Phase III studies showed that the drug was associated with a lower rate of central nervous system toxicities compared with Sustiva (efavirenz).

German researchers conducted a retrospective study of 1,704 people who started taking an integrase inhibitor between 2007 and April 2016. Between them, the cohort started 1,950 integrase-inhibitor-containing regimens and were followed for a median 11.5 months to 36 months, depending on which of the three integrase inhibitors—Tivicay, Vitekta (elvitegravir) or Isentress (raltegravir)—they started.

Overall, the rate of drug discontinuation due to any adverse health event was greater among those who took Vitekta, compared with those taking one of the other two integrase inhibitors.

But looking at just drug discontinuation rates during the first 12 months after starting an integrase inhibitor, the researchers found the respective rates of those who stopped due to any adverse health event and those who stopped due to a neuropsychiatric event to be: 7.6 percent and 5.6 percent for those taking Tivicay; 7.6 percent and 0.7 percent for those taking Vitekta; and 3.3 percent and 1.9 percent for those taking Isentress.

Considering those who stopped Tivicay due to neuropsychiatric side effects, the researchers found that women were 2.64 times more likely to do so than men; those 60 years of age and older were

2.86 times more likely to do so than those who were younger; and those who started Ziagen at the same time as Tivicay were 2.42 times more likely to do so than those who did not start Ziagen along with Tivicay.

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