Treating HIV With Tivicay Alone May Work for Those Treated Early

Previous studies found Tivicay monotherapy was subpar, but this trial switched people to the drug who had started combo treatment early.

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Switching people with HIV from a combination antiretroviral (ARV) regimen to treatment with Tivicay (dolutegravir) alone, known as monotherapy, may be effective for those who started ARVs within six months of infection, reports Infectious Disease Advisor.

Various randomized controlled trials investigating Tivicay monotherapy have found it does not suppress HIV as effectively as standard combination ARV treatment. The authors of one study concluded that switching people with the virus to such single-ARV treatment was neither safe nor ethical. However, such studies included participants who began HIV treatment more than six months after infection.

Note that Juluca (dolutegravir/rilpivirine) includes Tivicay. When Juluca was approved in November 2017, it became the first complete ARV regimen to include only two medications. ViiV Healthcare is currently investigating a combination of Tivicay and Epivir (lamivudine) as a two-ARV regimen.

Publishing their findings in Clinical Infectious Diseases, researchers in the new study recruited 99 people with HIV who had started ARV treatment within 180 days of a documented infection and had sustained a fully suppressed viral load for at least 48 weeks before entering the study. The participants were randomized 2-to-1 to switch from combination ARV treatment to receive Tivicay monotherapy (67 participants did so) or to stay on their same combination regimen (32 did so) for 48 weeks.

At the 48-week mark, everyone in the study had a fully suppressed viral load. The study authors concluded, therefore, that Tivicay monotherapy was noninferior to, or as effective as, combination ARV treatment among those who began HIV treatment early in the course of their infection.

Among those on Tivicay, the total amount of HIV DNA in their cells declined during the study. This suggested that the viral reservoir did not get replenished during this time.

HIV RNA remained undetectable in all cerebrospinal fluid samples taken, including among 23 people in the Tivicay group and 14 in the combination-ARV group at the study's outset, and among

a respective 10 and two people in each group at week 48.

During the study, the participants experienced no significant changes in their kidney function, markers of proximal renal tubulopathy (a serious kidney condition) or lipid test results.

The study authors speculated that Tivicay monotherapy's success in this study was likely driven by the early initiation of ARV treatment. By treating HIV soon after infection, participants likely had a smaller viral reservoir, less diversity in their viral population and lower immune activation—all factors that would yield a population of virus less likely to evade single-ARV treatment.

The study was limited by its relatively small size and by the fact that follow-up lasted only 48 weeks. The authors called for trials including longer follow-up as well as studies that stratify their findings according to the time between HIV infection and the start of ARV treatment as well as by the size of the reservoir.

To read the Infectious Disease Advisor article, click here.

To read the study abstract, click here.

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