Long-Acting Injectable Cabenuva May Not Require Oral Lead-In

A study found no difference in outcomes based on whether participants took oral meds for a month before switching to injectables.

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People with HIV who switch their antiretroviral (ARV) treatment to long-acting injectable Cabenuva (cabotegravir/rilpivirine) may not have to take a four-week oral lead-in of the two drugs in the monthly regimen. A recent clinical trial found no difference in outcomes based on whether participants went directly from taking Triumeq to receiving the monthly Cabenuva injections or first took four weeks of a daily pill form of the regimen and then started the injections.

Researchers presented findings from the Phase III randomized, open-label FLAIR trial of Cabenuva at the HIV Drug Therapy Glasgow meeting.

The trial enrolled people with HIV who had never been treated for the virus. First, they received Triumeq (dolutegravir/abacavir/lamivudine). Those who achieved a fully suppressed viral load at the end of 20 weeks were evenly randomized to either stay on Triumeq or to switch to Cabenuva. A total of 283 participants ended up in each of the two study arms.

Those in the Cabenuva group first received a lead-in of oral versions of the two drugs in the regimen, cabotegravir and rilpivirine. After at least four weeks of that treatment, they were switched to monthly injectable Cabenuva.

After two years, the researchers concluded that long-acting injectable Cabenuva was as effective at suppressing HIV as Triumeq.

At week 100 of the study, those in the Triumeq arm could elect to switch to Cabenuva. They could either start the long-acting regimen directly (111 participants did so), or they could take four weeks of the oral lead-in before starting the monthly injections (121 participants). Or they could withdraw from the study.

Twenty-four weeks later, one participant each (less than 1%) in the group that started the injections immediately and in the group that took the oral lead-in had a viral load of 50 or greater. A respective 99% and 93% of the two groups had a viral load below 50.

One participant in the group that started the injections immediately developed virologic failure—meaning two consecutive viral loads of 200 or higher—at week 112 of the study.

Adverse health events leading participants to withdraw from the study were infrequent. One person in the group that transitioned directly to injectable Cabenuva experienced a severe drug-related adverse health event—specifically, Hodgkin lymphoma.

The proportion of participants experiencing serious adverse health events was comparable between the two groups. Overall, injectable Cabenuva proved well tolerated. The most common adverse health events were injection-site reactions, which were mild or moderate in severity.

The study authors concluded that the trial's evidence suggests that long-acting injectable Cabenuva is a well-tolerated and effective maintenance therapy.

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