Cabenuva Every Two Months Maintains Viral Suppression for Three Years

The every-other-month schedule of injectable cabotegravir plus rilpivirine enables some people to take HIV treatment just six times a year.

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People who received Cabenuva (injectable cabotegravir plus rilpivirine) every other month were as likely to maintain viral suppression as those who received the injections every month, according to three-year follow-up data from the ATLAS-2M study presented at the Conference on Retroviruses and Opportunistic Infections 2022 (CROI 2022). However, those using the less frequent dosing schedule appeared more likely to experience treatment failure.

Cabenuva consists of a long-acting formulation of ViiV Healthcare's integrase inhibitor cabotegravir plus an injectable version of Janssen's non-nucleoside reverse transcriptase inhibitor rilpivirine. The regimen involves two separate injections in the buttocks administered by a health care provider.

The Food and Drug Administration initially approved Cabenuva as a once-monthly regimen in January 2021 and approved the every-other-month schedule in February 2022. It is indicated as maintenance therapy for adults who have achieved viral suppression on daily oral antiretrovirals, have no history of treatment failure and have no known or suspected resistance to either cabotegravir or rilpivirine.

The Phase III ATLAS study, which included more than 600 participants who started with an undetectable viral load on a standard daily oral regimen, showed that 93% of people who switched to once-monthly Cabenuva maintained an undetectable viral load (below 50 copies) at 48 weeks, as did 96% of those who stayed on their daily regimen.

The follow-up ATLAS-2M trial (NCT03299049) compared once-monthly and every-other-month dosing of the injectable regimen. The study included 654 participants with an undetectable viral load who switched from a daily oral regimen and 391 people who rolled over from the monthly Cabenuva arm of the original ATLAS trial. About 70% were men, and the median age was 42 years. Three quarters were white, and 18% were Black. The median CD4 count exceeded 600.

The participants were evenly randomized to receive injections of either 400 milligrams of cabotegravir and 600 mg of rilpivirine every four weeks or 600 mg of cabotegravir and 900 mg of

rilpivirine every eight weeks after a two-week oral lead-in period using cabotegravir and rilpivirine pills (Vocabria and Edurant, respectively).

At CROI 2020, Turner Overton, MD, of the University of Alabama at Birmingham, presented 48-week results from the trial, showing that 94% of participants in both treatment groups had a fully suppressed viral load, indicating that the less frequent schedule was noninferior to monthly dosing. At CROI 2021, researchers reported 96-week results, showing that 90% of people in the once-monthly group and 91% in the every-other-month group maintained an undetectable viral load.

At this year's CROI, Overton presented further follow-up results at 152 weeks. At this point, 86% in the once-monthly group and 87% in the every-other-month group had an undetectable viral load, while 1% and 3%, respectively, had a viral load of 50 or higher. More people in the once-monthly group withdrew from the study or were missing data, so the viral suppression rates ended up being statistically equivalent. Of note, more people in the once-monthly group discontinued due to the frequency of visits (10 versus 4, respectively) or intolerability of injections (8 versus 1).

While viral suppression rates were high using either dosing schedule, the greater frequency of treatment failure in the every-other-month group could be cause for concern.

Over three years, a total of two people (less than 1%) in the once-monthly group and 11 people (2%) in the every-other-month group met the criteria for confirmed virological failure (CVF), defined as two consecutive viral load measurements above 200 copies. Commenting on Twitter, Laura Waters, MD, of the U.K. National Health Service's Mortimer Market Centre in London, calculated that the risk of virological failure was 1 in 200 in the once-monthly group compared with 1 in 40 in the every-other-month group.

> 2 more VF in 2M arm gives a 1.7% difference favouring 1M with confidence interval not crossing zero this is a significant difference? Put simply at year 3 the risk of VF on 1M is 1 on 200 & on 2M 1 in 40
>
> — Laura Waters ???????? (@drlaurajwaters) February 14, 2022

In both groups, most treatment failures occurred during the first 48 weeks. Two people in the every-other-month group but none in the once-monthly group experienced CVF between week 96

and week 152. Overall, 60% of people with confirmed virological failure had two or more risk factors, including preexisting rilpivirine resistance mutations, HIV subtype A6/A1 or obesity. Most had integrase and rilpivirine resistance mutations at the time of treatment failure, but 12 of the 13 were able to regain viral suppression after switching to an alternative regimen.

Two additional analyses reported at CROI 2021 suggested that sticking to the dosing schedule is especially important for those on the every-other-month schedule. Researchers presented modeling data showing that delaying cabotegravir or rilpivirine injections by up to a week should have minimal impact, but longer delays could be a problem. People who need to miss an injection can use Vocabria and Edurant pills as a "bridging" strategy. However, no one with CVF in ATLAS-2M received injections more than a week after a scheduled visit date.

As seen at weeks 48 and 96, Cabenuva continued to be safe and well tolerated. Only 2% of participants in both groups experienced severe treatment-related adverse events. The most common side effect was injection site reactions, most often pain. However, this was usually mild to moderate and lasted a median of three days. Only 1% in both groups reported severe injection reactions, and 2% to 3% withdrew from the study for injection-related reasons. The number of participants reporting injection site reactions at each visit decreased over the first year and remained consistent thereafter.

What's more, participants reported greater satisfaction with Cabenuva compared with daily oral treatment, and they preferred every-other-month to once-monthly dosing. Previous analyses found that reasons for preferring injections included greater convenience, not having to think about HIV treatment every day and not having pill bottles that could reveal their HIV status.

Click here to read the study abstract.

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