Kaletra Maintenance Monotherapy Holds Up Over 96 Weeks

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People who switched to Kaletra (lopinavir plus ritonavir) monotherapy after six months of combination antiretroviral (ARV) therapy were as likely as people who stayed on a three-drug regimen to maintain undetectable viral loads, according to a study published in the June issue of the *Journal of Acquired Immune Deficiency Syndromes*.

Though ARV therapy has become both more potent and more tolerable in recent years, multiple-drug regimens can still lead to troubling side effects. Moreover, surveys of people living with HIV indicate that many prefer to take the lowest amount of drugs and pills as possible.

To reduce side effects and simplify treatment, researchers have been interested in the use of Kaletra alone (monotherapy). However, studies have documented that patients initiating therapy with Kaletra alone are unable to keep their viral loads undetectable for as long as those using Kaletra plus two other ARVs.

Researchers with the OK04 study took a different approach to the question of monotherapy. They enrolled 198 people who had completely suppressed virus on a three-drug regimen for six months and then randomized them to either stay on that regimen or switch to a maintenance regimen containing only Kaletra. In an earlier look at the data over 48 and 96 weeks, researchers with the study reported that monotherapy appeared to be nearly as potent as combination therapy. Now, Jose Arribas, MD, from the Universidad Autónoma de Madrid, and his colleagues offer a more detailed look at the 96-week data.

Arribas's team found that monotherapy and combination therapy were roughly equal. In the monotherapy group, 77 percent maintained a viral load under 50 copies over 96 weeks, compared with 77.6 percent on combination therapy. The authors also compared the number of people who failed treatment in either arm and who developed protease inhibitor (PI) resistance. Over 96 weeks, only 2 percent of people in either group developed PI resistance mutations.

As hoped, fewer people on the monotherapy arm had to stop treatment because of serious side effects: Eight people on the triple-drug therapy arm had to discontinue treatment for this reason, while no one on monotherapy did. Rates of adherence were roughly the same in both groups, and people on monotherapy had a somewhat greater increase in CD4 cells compared with people on combination therapy. Ultimately, the authors said, switching to monotherapy after a period of viral

suppression may be a reasonable alternative.

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