Dolutegravir + 3TC as maintenance therapy—a pilot study

Dolutegravir (Tivicay and in Triumeq) is a powerful integrase inhibitor and is being tested in simplified regimens—consisting of two drugs—to maintain viral suppression in people who have previously used combinations containing three anti-HIV drugs.

Researchers in the U.S. conducted a randomized 48-week pilot study (called Aspire) of dolutegravir + the nuke (nucleoside analogue) 3TC vs. current ART regimen (CAR) in people who had achieved a viral load less than 50 copies/mL. The combination of dolutegravir-3TC was found to be similarly effective as standard three-drug ART. Larger studies to better assess the effectiveness and safety of dolutegravir-3TC as maintenance therapy are planned.

**Study details**

Researchers assessed data from 89 participants randomly assigned to dolutegravir-3TC (44 people) or CAR (45 people). Their average profile upon entering the study was as follows:

- age – 47 years
- 88% men, 12% women
- CD4+ count – 680 cells/mm³

Participants did not have the following:

- a history of virological failure after being on their previous regimens for more than one year
- HIV that was resistant to 3TC or other nukes or integrase inhibitors
- hepatitis B virus (HBV) co-infection

**Results**

Rates of virological success—that is, the proportions of participants who continued to have a suppressed (less than 50 copies/mL) viral load at week 24—were distributed as follows:

- dolutegravir-3TC – 93%
- CAR – 91%

Rates of viral suppression at week 48 were distributed as follows:

- dolutegravir-3TC – 91%
- CAR – 89%

Overall, 92% of participants disclosed that they had perfect adherence.

Increases in CD4+ cell counts were as follows:

- dolutegravir-3TC – 38 cells/mm³
- CAR – 28 cells/mm³

**Other results**

In general, participants who received dolutegravir-3TC had minimal changes to lipids (cholesterol, triglycerides) and measures of kidney health.
Severely abnormal lab tests were distributed as follows:

- dolutegravir-3TC – four people; two cases of higher-than-normal blood sugar, one case of abnormal bad cholesterol (LDL-C) and one case of elevated liver enzymes (ALT)
- CAR – three people; all had elevated levels of the waste product bilirubin in their blood

Due to the small size of the study, it is not possible to say if the lab test abnormalities reported among participants taking dolutegravir-3TC were caused by those drugs.

There were no neuropsychiatric symptoms reported by participants on either study regimen.

**Bear in mind**

In this randomized study, the use of dolutegravir-3TC as maintenance therapy was similar in effectiveness and safety to standard ART. However, the study is small and not definitive. The results of this study provide a rationale for the larger studies that are planned to better understand the effects of dolutegravir-3TC.

—Sean R. Hosein

REFERENCE:

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