Switch From Efavirenz to Intelence Improves Side Effects in Some

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People on a regimen containing efavirenz (found in Sustiva and Atripla) who have neurological side effects or abnormal cholesterol or triglycerides (lipids) may see improvements if they switch to Intelence (etravirine). These data were published in two separate studies in the January 2 issue of AIDS.

Efavirenz is one of the most commonly used antiretrovirals (ARVs) in the developed world for people starting HIV treatment for the first time. It has proved over numerous studies to be both potent and relatively easy to take. It also has sometimes troubling side effects, notably central nervous system (CNS) side effects and lipid abnormalities. In turn, alternatives to efavirenz, including the non-nucleoside reverse transcriptase inhibitors (NNRTI) Viramune (nevirapine) and the newest member of the NNRTI family Intelence have been explored in clinical trials.

Intelence was approved in 2008 to treat people who have resistance to other medications, but it is not yet approved to treat people who haven't taken antiretroviral (ARV) therapy before. More recently, researchers have been experimenting with Intelence to determine whether it might have advantages earlier in the course of treatment over currently available drugs.

One such study, conducted by Laura Waters, MD, from the Chelsea and Westminster Hospital in London, and her colleagues, tested a switch from Sustiva to Intelence in people who had fully suppressed virus on Sustiva, but who had persistent CNS side effects.

In the study, 18 people switched to Intelence immediately, while 20 were switched after 12 weeks (delayed group). During the initial 12 weeks, people didn't know whether they had switched or not, because dummy drugs were used to represent either Intelence or Sustiva. After 12 weeks, everyone was openly offered Intelence.

At the beginning of the study, roughly 90 percent of the study participants complained of moderate to severe CNS side effects, including depression, anxiety, difficulty sleeping, vivid dreams and daytime sleepiness. Twelve weeks into the study, all of the study volunteers were surveyed again about their neurological status.

Switching to Intelence did result in improvements in CNS side effects. In the group who switched to Intelence immediately, the proportion reporting moderate to serious side effects dropped to 60

percent. In those who delayed switching, there was little change. After 12 weeks, those in the immediate switch arm did not continue to improve, but those who delayed switching did see some improvement.

When Waters and her team analyzed the specific types of side effects that improved, they found that people's abnormal dreams and level of anxiety significantly diminished when they switched to Intelence, but that other CNS effects remained largely the same. The study, however, was not large enough to determine how much each type of side effect improved.

Improvements were also seen in cholesterol and triglyceride levels from switching to Intelence.

In the second study, Alain Nguyen, PhD, from the University of Geneva in Switzerland, and his colleagues compared Intelence with Sustiva in 55 people who were doing well on a Sustiva regimen and who were not complaining of Sustiva CNS effects. The purpose of the study was to determine whether subtle CNS side effects from Sustiva might become apparent, and therefore improve, if a person switches to Intelence.

The study had what is called a crossover design. In this case, for the first six weeks, 27 people stayed on Sustiva and 28 switched to Intelence. For the second six weeks, those who'd been switched to Intelence went back to Sustiva, and those who'd initially remained on Sustiva switched to Intelence. Because the study used dummy pills, neither the participants nor their doctors knew who was in which group.

In this study, the participants did not see any type of improvement in anxiety, depression or sleep quality from switching to Intelence. Nor, when asked, did a significant proportion state a preference for one drug over the other. There were, however, significant improvements in cholesterol and triglycerides from Intelence.

Though Intelence is approved to be taken twice daily, it was used once daily in both studies, without any viral load rebounds.

In conclusion, the authors of both studies noted that Intelence appears to be a safe and reasonable alternative for people on Sustiva who are having lipid abnormalities, and Waters and her colleagues commented that switching could also result in improvements in those on Sustiva with persistent CNS side effects.

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