

HIV therapy just got easier: Fewer drugs may be needed for treatment-experienced patients

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A new multi-site study reveals patients with drug-resistant HIV can safely achieve viral suppression – the primary goal of HIV therapy – without incorporating the traditional class of HIV medications into their treatment regimen. Karen Tashima, M.D., director of the HIV Clinical Trials Program at The Miriam Hospital, served as study chair.

The AIDS [Clinical Trials](#) Group (ACTG) Network's OPTIONS Trial proves, for the first time, that treatment-experienced [patients](#) can leave out this class of medication, known as nucleoside reverse transcriptase inhibitors (NRTI), as part of the regimen. These results could change treatment guidelines, lessen side effects and increase adherence rates, the researchers say.

Tashima and colleagues presented the results from the 48-week study at the annual Conference for [Retroviruses](#) and [Opportunistic Infections](#) (CROI) in Atlanta on March 6.

"We are so comfortable clinically with the NRTI class that we think we must always use at least one drug from this class in treatment. However, some patients have developed within-class resistance, making the NRTIs less effective overall. Therefore, drugs from this class may not be needed if the new treatment plan contains more effective medications," said Tashima, who also leads ACTG's clinical research site at The Miriam Hospital.

"There were a few new drugs coming out at the same time and we decided to turn the question around. Instead of having patients take their current medications from the NRTI class as well as these new drugs from different classes, we asked half of the [study participants](#) to add NRTIs and half of them to leave out NRTIs from their new treatment plan. We were able to take the usual study paradigm and turn it around," she added.

Treatment-experienced patients can develop resistance to therapy due to poor adherence, said Richard Haubrich, M.D., the study's co-chair and professor of medicine at University of California at San Diego. Designing a treatment plan using [new drugs](#) from new classes and omitting NRTIs leads to fewer pills, and hopefully, better adherence.

"There are several options for treatment naïve patients, but not as many for treatment-experienced. The HIV research field accepted that nucleosides would be an important component for multiple class-experienced patients," said Haubrich. "However, our results were very clear. We can safely exclude NRTIs, giving physicians a new paradigm for ART prescription in clinic and potentially changing treatment guidelines."

To ensure eliminating NRTIs from their [treatment regimen](#) would not be detrimental for [viral suppression](#), investigators used a web utility to review each of the 413 study participants' study records to determine optimal treatment plans. This tool allowed all of the study's investigators to consult together on each study participant, offering the best plan for treatment.

The OPTIONS Trial, also called A5241, included ACTG sites from around the country as well as sites from the International Maternal Pediatric Adolescent AIDS Clinical Trials group and the Adolescent Medicine Trials Network. Study volunteers needed to be at least 16 years

old and show treatment experience or resistance to their current HIV medications. Most of the A5241 participants had been on ART for 10 years or more.

Traditional antiretroviral therapy consists of medications from the nucleoside reverse transcriptase inhibitor class, including tenofovir, azidothymidine and lamivudine. The new medications studied included darunavir and tipranavir from the protease inhibitor class of HIV medications, maraviroc from the CCR5 antagonist class, raltegravir from the integrase inhibitor class, etravirine from the non-nucleoside reverse transcriptase inhibitors class and enfuvirtide an injectable drug from the fusion inhibitor class.

Patients will continue on study for a total of 96 weeks to ensure virologic suppression is maintained.

"There is no question that the results show what we had set out to prove – a treatment-experienced patient will not lose virologic suppression by omitting NRTIs," said Tashima. "We are so excited to show this data."

Provided by Lifespan

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