Tivicay Bests Non-Integrase Therapy as First- and Second-Line HIV Treatment For Kids

A high-quality trial should improve access to dolutegravir for children worldwide.

December 30, 2021 By Heather Boerner

The Department of Health and Human Services (DHHS) already named Tivicay (dolutegravir) as one of two preferred treatments for children living with HIV, but a clinical trial published in the New England Journal of Medicine confirms it: HIV regimens containing the integrase inhibitor resulted in more children achieving an undetectable viral load at 96 weeks than regimens without dolutegravir.

The ODYSSEY trial enrolled 707 children, mostly in Uganda, Zimbabwe and South Africa, to be randomly assigned to receive either a regimen containing dolutegravir or one based on a protease inhibitor or a non-nucleoside transcriptase inhibitor (NNRTI).

The children had a median age of 12, half were girls and 28% had a viral load of at least 100,000 copies—that is, untreated HIV.

At 96 weeks, 14% of children receiving dolutegravir-based regimens still had an detectable viral load, indicating that the treatment had failed. On the protease inhibitor or NNRTI side, 22% experienced treatment failure. That's a 40% lower chance of having treatment fail—or a 60% increase in treatment success.

The children in the trial didn't receive the other integrase inhibitor-based regimen the DHHS recommends for children as first-line treatment: Biktarvy (bictegravir, emtricitabine/tenofovir alafenamide). The U.S. guidelines list Biktarvy as a regimen of choice for first-line treatment of children who are at least 6 years old.

What the study does confirm, said Cissy Kityo, MD, the site investigator for the study at the Clinical Research Centre in Uganda, is previous data showing that adult doses of dolutegravir are safe for older children. And that will simplify offering the pills across Africa.

"Simplifying the dosing is crucial," said Kityo in a press release. "Older children being able to take the same tablets as adults immediately opens access to dolutegravir for the majority of children

living with HIV. It greatly simplifies procurement for national health systems in low- and middle-income countries and lowers costs."

Diana Gibb, MD, ODYSSEY's principal investigator and a pediatrician with University College London's Clinical Trials Unit, agreed, saying that the study findings can improve equity in health outcomes for children living with HIV worldwide.

"Medical treatments for children often lag woefully behind those of adults because of the separate formulations and studies that are needed," she said in the press release. "With the evidence from ODYSSEY which used simplified dosing, this treatment gap has been reduced and we hope that countries can quickly scale up children's access to treatment globally."

Click here to read the study abstract.

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