New HIV drug formulation could improve treatment outcomes for children worldwide

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Researchers at the University of Colorado Anschutz Medical Campus have helped confirm the dosing, safety and effectiveness of a drug formulation designed for treating children with human immunodeficiency virus (HIV).

The study was published today in *The Lancet HIV* and reveals a new dispersible formulation and an immediate-release tablet containing three medications—dolutegravir, abacavir and lamivudine—in a single fixed dose combination (FDC) formulation is safe, well tolerated, and effective for treating children with HIV. The dosing based on the concentrations of each medication in the blood was also appropriate.

"This is the first FDC containing dolutegravir that can be used for children from 13 to 88 pounds," said Kristina Brooks, PharmD, an assistant professor in the University of Colorado Skaggs School of Pharmacy and Pharmaceutical Sciences at CU Anschutz. "HIV treatment in children has historically been challenging as it requires the use of multiple tablets and liquids that don't always taste the best, and can be challenging to administer."

Dolutegravir, abacavir and lamivudine have been shown to be safe and effective worldwide to treat HIV. Brooks and Jennifer Kiser, PharmD, Ph.D., worked with a team of investigators through the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network to look at both an existing immediate release tablet and a new formulation of dispersible release tablets containing all three drugs to see if it would yield the same positive results they have seen in adults and adolescents.

"57 children were enrolled across five weight bands in four countries, of which 54 children used the new combination over 24 weeks. In 98 percent of the participants who continued the study drug, the amount of HIV in the blood remained suppressed below 200 copies/mL at week 24. The safety, tolerability, and effectiveness of these formulations look very positive," Brooks said.

Child-friendly FDC formulations for HIV are limited. Brooks said this new formulation could help enable continuity of treatment, improve

treatment outcomes and make it easier for caregivers responsible for dispensing the drugs. This study also helped support recent labeling updates by the U.S. Food and Drug Administration to expand the use of this formulation to children aged at least 3 months and weighing at least 13 pounds.

There are currently two million children living with HIV across the globe. Only 52 percent are on therapy, and despite making up only four percent of the worldwide HIV population, children account for 15 percent of AIDS-related deaths. Studies like this are vital to improve these outcomes and to make medication more accessible around the world.

"We must continue to pursue child-friendly treatment options to overcome the current global disparity in treatment outcomes between children and adults," Brooks said.

Some of the children who were in the initial trial are still on the new drug formulation through an open access program. The longer-term safety, tolerability, and effectiveness through 12 months of treatment is under analysis now and will be reported separately.

More information: Kristina M Brooks et al, Pharmacokinetics, safety, and tolerability of dispersible and immediate-release abacavir, dolutegravir, and lamivudine tablets in children with HIV (IMPAACT 2019): week 24 results of an open-label, multicentre, phase 1–2 dose-confirmation study, *The Lancet HIV* (2023). DOI: 10.1016/S2352-3018(23)00107-8 , www.thelancet.com/journals/lan … (23)00107-8/fulltext

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