

## Drug to treat HIV in children shows promise via national study

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(Medical Xpress) -- For children and adolescents with HIV infection, the recent Food and Drug Administration (FDA) approval of the use of raltegravir, an antiretroviral drug that slows the spread of HIV infection, offers a new weapon to treat HIV infection in children. So says Sharon Nachman, M.D., Associate Dean for Research and Professor of Pediatrics, Stony Brook University School of Medicine, and the Principal Investigator and Study Chair of a national multicenter clinical trial that studied the safety and efficacy of raltegravir in HIV-infected children and adolescents.

The FDA approved raltegravir for use with other [antiretroviral drugs](#) for the treatment of [HIV infection](#) in children and adolescents ages 2 to 18 years on December 21. Approved for use in adults in 2007, raltegravir is part of a class of medications called HIV integrase inhibitors.

In the clinical trial, sponsored by the National Institute of Health's National Institute of Allergy and Infectious Diseases, all of the 96 patients enrolled had previously been treated with a regimen of other HIV medications before raltegravir. After being treated for 24 weeks with raltegravir, 53 percent of the patients had an undetectable amount of HIV in their blood.

“Raltegravir is an important new option for children with HIV. The trial shows it has an excellent efficacy profile in children with HIV who have failed other regimens and is also effective against the virus regardless where the child lives around the world,” says Dr. Nachman. “The data

also shows no significant toxicities or interactions with other HIV medications.”

The formulation of raltegravir in children is a pill that can be taken twice daily, with or without food. For younger patients, there is a chewable form. Dr. Nachman points out that in addition to the drug being an important new option for pediatric patients, the formulations available are more convenient and may help increase patient compliance.

The FDA indicates that the most commonly reported severe, treatment-related side effects in patients taking raltegravir include insomnia and headache. The frequency of these side effects is similar in adults and children.

Dr. Nachman says that the study of the use of raltegravir to treat HIV in [children](#) and adolescents will continue. Each child enrolled will be followed for five years. During that period, Dr. Nachman and colleagues will continue to evaluate efficacy and any long-term complications of the medicine in the patient population.

The study provides the only pediatric data on the use of raltegravir in patients ages 2 to 18 years. [Patients](#) are enrolled through Stony Brook and other study locations nationwide. Dr. Nachman says that one of the next steps to advance the study is to evaluate a novel baby formulation.

Provided by Stony Brook University

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