

# **Injectable HIV medication is superior to oral medication for patients who frequently miss doses, study finds**

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When a person is diagnosed with HIV, they are placed on a lifelong HIV treatment regimen, called antiretroviral therapy, to keep the virus under control. But for many people, having to take medicine every day can be

a struggle for a variety of reasons, resulting in missed doses that could potentially lead to a decline in their health.

To address this issue, Jose Castillo-Mancilla, MD, a volunteer associate clinical professor in the Division of Infectious Diseases at the University of Colorado Department of Medicine, co-chaired a national clinical trial starting in 2014 with Aadia Rana, MD, a professor at the University of Alabama. Named the Long-Acting Therapy to Improve Treatment Success in Daily Life (LATITUDE) study, it investigated whether switching to a monthly injectable form of anti-HIV medicine, rather than taking daily oral medication, was a better therapy option.

Nearly a decade later, interim data from the clinical trial showed what Castillo-Mancilla had long suspected: Long-acting [antiretroviral therapy](#) was superior in suppressing HIV replication compared to daily oral medication. In fact, its superiority was significant enough that a National Institutes of Health Data and Safety Monitoring Board recommended that all eligible study participants take the long-acting medication.

"Finding out that the results of our study showed what we had hoped, and that we were able to demonstrate that this treatment strategy can help these patients, was an incredible feeling," Castillo-Mancilla says. "I have to admit, I shed many tears of joy."

## **The need for this study**

Castillo-Mancilla has been interested in helping people who have HIV since the late 1990s, when he was doing research at the National Cancer Institute in Mexico and saw very sick patients with advanced HIV.

For patients with HIV, achieving viral suppression, also known as being "undetectable," is important, he says. This means that a patient has controlled HIV and cannot transmit it to others.

"Having controlled HIV is crucial to prevent the progression of the disease from HIV into AIDS," he says. "Being undetectable is also important to prevent the development of drug resistance and to prevent other complications such as cardiovascular disease."

However, to achieve this, consistently taking medicine is important—something that can be a struggle for some. Up to 25% of people prescribed conventional antiretroviral therapy stop taking the medication for some period, the [NIH](#) said in 2019.

"Committing to life-long therapy is a very difficult goal to accomplish, even for the most dedicated patient," Castillo-Mancilla says. "Many of our patients face competing priorities that make it difficult for them to take pills every day. These include barriers such as employment, childcare, transportation, stigma, and active mental illness or substance use, among others."

Developing a study that focused on a patient population that has trouble taking daily medications was important because, traditionally, these patients have not been included in [clinical trials](#) despite representing a vulnerable population for whom the currently available treatment options are not working, he says.

"Compound that with the fact that one-third of people living with HIV in the U.S. struggle with maintaining viral suppression," he says.

"Identifying new successful strategies to help these patients can be crucial in our effort to end the HIV epidemic."

## **Creating LATITUDE**

Castillo-Mancilla worked with Rana to conceptualize the LATITUDE study in 2014—when long-acting HIV therapy was still being developed, he says. They wanted to find out if two long-acting injectable

formulations of antiretroviral therapy—specifically the drugs rilpivirine and cabotegravir, which are administered every four weeks—would help people with HIV who struggle to take daily medication to become and remain undetectable.

Together, with their study team, Castillo-Mancilla and Rana wrote proposals that were presented to [Advancing Clinical Therapeutics Globally \(ACTG\)](#), which was previously known as the AIDS Clinical Trials Group. They were able to create a study protocol and partner with ViiV Healthcare, which provided the study drug.

Through extensive work and collaboration, the open-label clinical trial began operating, involving 31 sites across the country, including Puerto Rico, and enrolling about 350 volunteers. Castillo-Mancilla served as study co-chair with Rana until he transitioned to working for ViiV Healthcare in 2023.

## **How the interim data shifted the study**

The LATITUDE study was broken down into a series of steps. Originally, as part of step two, participants would either continue receiving oral standard-of-care medication for HIV, or they would transition to the long-acting medication.

That is until interim data from a randomized trial showed that long-acting antiretroviral therapy was superior in suppressing HIV replication compared to daily oral medication.

Based on this interim data, in February of this year, the Data and Safety Monitoring Board recommended halting randomization and inviting all eligible study participants to take the long-acting medication. NIH accepted this recommendation, which means step two of the study has halted and participants are not being randomized anymore; instead, all

eligible participants are able to get the long-acting [medication](#).

"The fact that step two was halted does not mean that the study was stopped. It just means that every study participant is now being offered long-acting therapy," Castillo-Mancilla says. "In fact, the study has a step three that lasts 48 weeks, with the goal of evaluating the durability of the treatment strategy."

Once participants complete step three and end their participation in the study, they can decide in conjunction with their [health care provider](#) whether they want to continue receiving long-acting injectable therapy or not.

"If they decide to continue this therapy, they may be able to obtain it through their regular clinical care and not as a study participant," he says.

## Looking ahead

Given the positive results the clinical trial has seen, the study team now aims to complete the study and disseminate the results to the medical community so patients can benefit from this, Castillo-Mancilla says.

"The main message for the medical community is that we have new treatment strategies for our patients who face barriers to adherence and cannot take daily medications," he says.

He wants patients with HIV to know that this is a new option that could help them achieve viral suppression—that goal of being "undetectable"—so they may live longer and healthier lives. It's a sentiment he hoped for nearly a decade ago, when the study originated.

"This clinical trial has been my life for the last 10 years. It allowed me to

meet and work with incredible colleagues and friends like Dr. Rana and colleagues at the ACTG and ViiV Healthcare," Castillo-Mancilla says. "Most importantly, it allowed us to contribute in the fight to end the HIV epidemic."

**More information:** The LATITUDE Study: Long-Acting Therapy to Improve Treatment SUccess in Daily Life (2023).  
[clinicaltrials.gov/study/NCT03635788](https://clinicaltrials.gov/study/NCT03635788)

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