Trial Launches of Long-Acting HIV Regimen for Those Nonadherent to Daily Meds

The trial will investigate whether injections of long-acting cabotegravir and rilpivirine yield a superior rate of viral suppression.

May 16, 2019 By Benjamin Ryan

The National Institutes of Health (NIH) has launched a trial of long-acting injectable HIV treatment given every four weeks for those who have not adhered well to a daily oral antiretroviral (ARV) regimen. The study will investigate whether randomizing such individuals to receive the injectable treatment will yield a higher rate of viral suppression after one year, compared with randomizing individuals to stay on daily oral treatment.

The injectable regimen includes long-acting formulations of ViiV Healthcare's cabotegravir and Janssen's rilpivirine. In April, ViiV applied for Food and Drug Administration (FDA) approval of the injectable regimen, so the agency will likely make a decision by the end of 2019.

Whether people with HIV will prefer to go to a clinic for a shot every month instead of taking daily ARV pills is an open question. However, this regimen may prove a good fit for those who adhere poorly to traditional oral regimens—hence, this new trial.

Called the Long-Acting Therapy to Improve Treatment Success in Daily Life (LATITUDE) trial, the study is funded by the National Institute of Allergy and Infectious Diseases (NIAID, a division of the NIH). It is being conducted by the AIDS Clinical Trials Group (ACTG) and is supported by the National Institute of Mental Health, the National Institute on Drug Abuse, ViiV and Janssen.

The study will enroll about 350 people with HIV who have documented lapses in their adherence to daily ARVs during the previous 18 months. They will be started on a daily oral ARV regimen and provided individualized support to encourage their adherence to the regimen and their retention in the study. Those with an undetectable viral load 24 weeks into the study will be randomized to keep receiving such standard of care for the virus or to receive the injectable treatment for one year.

Those in the injectable treatment arm will take an oral regimen of cabotegravir (which as a daily non–long-acting pill is marketed as Edurant) and rilpivirine for four weeks, after which they will be

transitioned onto the long-acting injectable formulation of this regimen and receive injections every four weeks for 48 weeks.

Participants will receive routine monitoring of their viral load and other indicators of immune health as well as any adverse health events.

At the end of the 52-week study period, those who were randomized to stay on the standard-of-care regimen will be given the option of switching to the long-acting treatment. Those randomized into the injectable treatment group will be permitted to stay on the treatment for an additional year if they choose.

The long-acting formulations of rilpivirine and cabotegravir remain in the body for months after each injection, long after they have dissipated to sub-therapeutic levels. Consequently, those who discontinue this treatment will receive an additional year of safety monitoring, during which they will be prescribed a daily oral regimen.

To read a press release about the study, click here.

To read more about the study, including how to enroll, click here.

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