Small Study Backs Safety of Stopping HIV Treatment During Cure Studies

This NIH study closely monitored 10 people with HIV who stopped antiretroviral treatment for weeks to months in a larger cure study.

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People with HIV participating in HIV cure studies who stop antiretroviral (ARV) treatment for a period during which they are closely monitored do not experience a sustained increase in the size of their viral reservoir or permanent damage to their immune function, according to a small study. This provides important reassurance for the ethics of enrolling participants in such cure studies.

Trials that seek to provide people living with the virus an opportunity to experience sustained periods off ARVs without a rebound of their viral load must currently put participants through what is known as an analytical treatment interruption (ATI) of their traditional HIV medications. This gives researchers a chance to observe how the virus behaves without the suppressive power of ARVs.

Important questions remain about the short- and long-term safety of ATIs. dTo address such questions, researchers at the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH), conducted a substudy of 10 people with HIV who participated in a clinical trial evaluating whether infusions of a broadly neutralizing antibody could yield a sustained period of controlled virus in the absence of daily ARVs. Participants in the larger study went through an ATI.

The study authors published their findings in PLOS Pathogens.

During their own ATIs, the 10 substudy participants saw their virus rebound between 22 and 115 days after going off daily ARVs, after which point they were put back on standard HIV treatment. During this period off ARVs, the size of the participants' viral reservoir increased along with their viral load. Additionally, they experienced various immune-cell abnormalities. Between six and 12 months after the participants restarted ARVs, their reservoir size and immune cell characteristics retreated to the levels seen before the ATI.

According to an NIH press release, "The findings support the use of ATI in clinical trials to evaluate the efficacy of therapeutic strategies aimed at achieving sustained ART-free remission. However, larger studies that do not involve any interventional drugs are needed to confirm and expand on

these results.”

This study’s researchers are currently conducting such a trial, monitoring how a short-term ATI impacts various immune-system-based and virus-based metrics among people with HIV.

To read a previous POZ feature article about the ethics of ATIs, click here.

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

To read the study, click here.
