# Experimental Antibody Delays but Does Not Prevent HIV Rebound

People treated with VRC01 maintained undetectable viral load for up to 42 weeks after stopping antiretroviral therapy.

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VRC01, a broadly neutralizing antibody being studied for HIV treatment and prevention, modestly delayed the return of viral replication after a closely monitored antiretroviral treatment interruption, according to a small study presented at the recent 9th International AIDS Society Conference on HIV Science (IAS 2017) in Paris.

Study participants who received IV infusions of VRC01 experienced viral rebound in a median of 26 days, compared with 14 days for those who received inactive placebo infusions. However, everyone did ultimately see a resurgence of the virus, Trevor Crowell, MD, of the U.S. Military HIV Research Program, reported.

Broadly neutralizing monoclonal antibodies are among the many experimental approaches that may contribute to a "functional cure" for HIV. Experts agree that completely eradicating HIV from the body will be difficult or perhaps even impossible, but a functional cure—or long-term remission—could allow people with HIV to stay off antiretroviral medications for lengthy periods without viral replication and its harmful consequences.

Broadly neutralizing antibodies work against a wide range of HIV strains. One of these antibodies, VRC01, targets HIV's CD4 binding site, preventing the virus from latching onto susceptible T cells.

Crowell presented findings from a study testing VRC01 in people who started antiretroviral therapy very soon after HIV infection. Starting treatment very early limits the size of the latent HIV reservoir, offering a better chance of achieving viral remission.

The RV397 study included 18 men in Thailand who started antiretrovirals during acute HIV infection (known as Fiebig stages I to III) and had a viral load below 50 copies per milliliter for at least two years. The median age was about 30, they had been on treatment for about three years on average and they still had high CD4 counts.

The study participants were randomly assigned to receive infusions of VRC01 (13 men) or placebo (five men) every three weeks. They stopped antiretrovirals at the time of their first dose. Infusions

were scheduled to continue for 24 weeks; at that point, those who maintained viral suppression could continue observation without further treatment for up to 24 more weeks.

Stopping treatment in people with HIV who are doing well on antiretroviral therapy is controversial, as studies have shown that treatment interruptions can be harmful. To minimize the risk, participants in this study were monitored every three to seven days, and they resumed treatment if they had a confirmed viral load above 1,000 copies/mL, their CD4 count fell below 350 or they showed signs of clinical disease progression.

The men who received VRC01 had a “modest” delay in viral resurgence compared with the placebo group, Crowell reported. The majority of participants in the VRC01 group experienced viral rebound within three to five weeks (median 26 days), while all but one participant in the placebo group had viral rebound within one to three weeks (median 14 days). All these participants restarted antiretrovirals and regained undetectable viral load.

One participant in the VRC01 group maintained undetectable viral load through 42 weeks. This 24-year-old gay man had started antiretroviral therapy during Fiebig stage III and was virally suppressed for about three years on a regimen of tenofovir disoproxil fumarate, lamivudine and efavirenz. However, he, too, ultimately experienced viral rebound and had his first detectable viral load measurement just days before the study presentation, Crowell said.

VRC01 was generally safe and well tolerated. One person had a severe skin rash after his first infusion and never underwent treatment interruption. There were no other serious adverse events. Infusion-related side effects included fatigue, headache, nausea and injection site pain, but these were similar in the VRC01 and placebo groups. No one developed acute retroviral syndrome or new drug resistance mutations.

This study found that VRC01 alone is unable to maintain viral suppression after stopping antiretroviral therapy, but it does show some activity and may have potential as part of a combination approach for achieving long-term HIV remission.

“These findings give us hope that combination therapies, especially those employing the newest and strongest monoclonal antibodies, may have some efficacy,” Crowell concluded.

VRC01 is also being studied for HIV prevention in the AMP (Antibody-Mediated Prevention) trial.

To read the study abstract, click here.

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