

# VRC01 antibody prolonged time to HIV viral rebound after treatment interruption

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A new study has shown that infusion of a broadly neutralizing antibody (bNAb) in virally suppressed, early treated volunteers was associated with a modestly delayed rebound of HIV after interruption of antiretroviral therapy (ART). The study, the first randomized controlled trial to demonstrate this effect of VRC01, was led by the U.S. Military HIV Research Program (MHRP) of the Walter Reed Army Institute of Research (WRAIR) and the Thai Red Cross AIDS Research Centre. MHRP presented findings from the study today at the 9th IAS Conference on HIV Science in Paris, France.

The study, called RV397, is part of a portfolio of MHRP's HIV remission research that seeks to find treatments to suppress the virus without a need for lifelong ART. Researchers evaluated the use of VRC01 in a small cohort of Thai men who were diagnosed and initiated ART within the first month of HIV infection, and who had been virally suppressed for about three years.

"This is the first time that the VRC01 antibody has been evaluated in people who started ART during acute HIV infection," said Dr. Trevor Crowell, the MHRP research physician who presented the findings. "We hypothesized that VRC01 might be more effective at suppressing HIV in the bloodstream of these volunteers than had been observed in people who started ART during the chronic phase of infection. These volunteers had a smaller HIV reservoir and less viral diversity, meaning they were less likely to have pre-existing resistance to the antibody."

Thirteen volunteers with undetectable viral loads were randomized into an intervention group that received VRC01, a broadly neutralizing antibody that inhibits multiple strains of HIV by adhering to the CD4 binding site on the virus. Five volunteers were randomized into a placebo group. Volunteers received infusions at the time of ART interruption and every three weeks thereafter, up to 24 weeks. If virus was detected in their blood, the infusions were stopped and ART restarted.

There was a delay in viral load rebound in people who received VRC01, which occurred at a median of 26 days versus 14 days in the placebo group. Seventeen of the 18 volunteers experienced viral rebound and reinitiated ART. One participant who received VRC01 was virally suppressed for 42 weeks post-treatment interruption, however within the last few days his viral load has become detectable.

"Although the delayed time to viral load rebound with VRC01 seen here is likely not clinically significant, it taught us two important lessons," said Dr. Jintanat Ananworanich, Associate Director for Therapeutics Research at MHRP. "It provides the basis for future studies in early treated people with combination bNAbs of higher potency, and we can now investigate the samples from this study to identify factors that might have contributed to the delay in rebound."

This is one of several functional cure studies MHRP is conducting in its acute infection cohort, RV254/SEARCH010, which is a collaboration with the Thai Red Cross AIDS Research Centre to identify acutely infected individuals and place them onto ART immediately. Researchers have found that this very early initiation of ART results in immune restoration and a very small or undetectable reservoir of HIV DNA.

**More information:** Abstract: Tuesday, July 25, 2:30-4:00 pm: Dr. Trevor Crowell, "HIV-Specific Broadly-Neutralizing Monoclonal Antibody, VRC01, Minimally Impacts Time to Viral Rebound Following

## Treatment Interruption in Virologically-Suppressed, HIV-Infected Participants who Initiated Antiretroviral Therapy during Acute HIV Infection"

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