Early HIV Vaccine Trial Builds on Moderately Successful Predecessor

By altering the components of the vaccine regimen, researchers drove promising antibody and immune-cell responses.

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By altering the components of the one vaccine ever to show any efficacy against HIV, researchers have succeeded in prompting participants' immune systems to develop promising antibody and immune-cell responses, according to research published in the Journal of Clinical Investigation. These findings from an early-stage clinical trial suggest that more advanced research is warranted.

The HVTN 105 study was a multicenter, randomized, double-blind Phase I trial led by Nadine Rouphael, MD, protocol co-chair and investigator at the Emory Center for AIDS Research, and Michael Keefer, MD, chair and professor in the department of medicine at the University of Rochester Medical Center. The trial was conducted by the HIV Vaccine Trials Network (HVTN), which is headquartered at the Fred Hutchinson Cancer Research Center, and was funded by the National Institute of Allergy and Infectious Diseases, which is part of the National Institutes of Health.

The trial investigated vaccine regimens that were retooled versions of the vaccine that showed a modest efficacy against the virus in the RV144 trial in Thailand a decade ago.

HVTN 105 enrolled 104 people at low risk for HIV, who were randomized to one of four treatment groups, T1 through T4. The median age of the participants was 27 years old, and 53% were male.

The participants received injections into the muscle at the study's outset and at months one, three and six. Those in group T1 received the protein AIDSVax B/E vaccine in the first two doses and then DNA boosters, known as DNA-HIV-PT123, for the second pair of doses. The DNA booster replaces the ALVAC vector used in the Thai trial. The T2 group received the same doses as those in T1, but in reverse order. Members of the T3 group received HIV DNA priming shots in all four doses, along with the protein in the last two doses. And those in T4 received the pairing of AIDSVax B/E and DNA-HIV-PT123 in all four doses.

For any shot that did not include both AIDSVax B/E and DNA-HIV-PT123, a placebo was included to stand in place of whichever of the two agents was not included.

Immune responses were detected in 80% to 100% of participants two weeks after the second dose of the protein vaccine. The highest such response was seen in the T3 and T4 groups, in which 95% to 100% of the participants developed antibodies against the gp120 HIV envelope protein as well as the V1V2 region of the HIV Env protein. Those in the T3 and T4 groups also developed the highest level of antibody-dependent cellular cytotoxicity and production of neutralizing antibodies against the virus. Additionally, all participants developed T-cell responses to the vaccine regimen.

The vaccines proved generally safe and well tolerated. Participants in the four groups produced IgA and IgG antibodies in different proportions, which led to differing side effects profiles.

Ultimately, this study found that administering both AIDSVax B/E and DNA-HIV-PT123 drove a greater immune response compared with what was seen in the Thai trial.

To read the study, click here.

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