New HIV Vaccine Trial in Americas and Europe Backed by Promising Earlier Study

The ASCENT trial found that the vaccine regimen that was advanced to the forthcoming Mosaico trial prompted a strong immune response.

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As the Phase III Mosaico HIV vaccine efficacy trial prepares to launch among men who have sex with men (MSM) and transgender individuals in the Americas and Europe, the vaccine regimen under investigation has been found to prompt a strong immune response in an earlier-stage trial.

Daniel J. Stieh, PhD, of Janssen Pharmaceuticals presented findings from the randomized, double-blind, placebo controlled Phase IIa ASCENT trial at the 10th International AIDS Society Conference on HIV Science in Mexico City (IAS 2019).

The randomized, parallel-group, placebo-controlled, double-blind Phase I/IIa APPROACH study, also presented at the conference, reached similar immunological findings about the basis of two variations on this same HIV vaccine regimen—findings that not only supported Mosaico's launch but also provided encouraging findings about the regimen currently being studied in the Imbokodo vaccine efficacy trial among women in Southern Africa.

ASCENT, also known as HPX2003/HVTN118/IPCAVD02, sought to determine whether adding an extra component to a vaccine regimen previously studied in other trials would optimize the breadth of the vaccine's impact on the immune system. Specifically, the trial added what is known as a Mosaic1 gp140 antigen (a protein that prompts an immune response) to the pair of injections that included clade C gp140.

The study recruited 152 HIV-negative adults between 18 and 50 years old in Kenya (5 people), Rwanda (40 people) and the United States (107 people). They were between 18 and 50 years old, and 59% were women.

The participants received four injections over a 48-week period. Twenty-six people were randomized to receive a placebo while the rest were randomized into two groups that received different versions of the vaccine. Those in the vaccine groups received what is known as Ad26.Mos4.HIV in all four of their injections. In the latter pair of injections, these individuals were

randomized to receive an addition of either clade C gp140 (26 people) or both the clade C and Moscaic1 gp140 antigens (100 people). Those third and fourth injections also included an aluminum phosphate adjuvant, meant to boost the immune response.

All the injections proved well tolerated. Most adverse health events among the participants were mild or moderate; there were no serious adverse events. None of the participants contracted HIV. (This was not an efficacy trial, however, so the lack of new infections should not be interpreted as proof that the vaccine prevents the virus.)

Both vaccine regimens demonstrated a strong immune response to HIV, specifically antibodies to the HIV envelope, or the outer shell of the virus. Even though the vaccine regimen that included both the clade C and Mosaic1 gp140 antigens provided half the dose of the clade C gp140 as used in those who did not receive the Mosaic1 gp140 antigen, this dose reduction did not blunt the vaccine's responses to clade C of the virus. In fact, those who received both antigens had an improved response to clade B of HIV compared with those who received just the one.

The vaccine also increased the level of CD4 cells that were primed to recognize the Mosaic Env viral antigen.

The study authors concluded that the ASCENT findings support the Mosaic trial's investigation of the vaccine regimen that included both the Mosaic1 and clade C gp140 antigens.

The participants will be followed for up to three and a half years past their last vaccination.

To read the study abstract, click here.

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