HIV Vaccines as Prevention
HVTN 505 Study Update

During a scheduled mid-point review of the study's data on April 22, 2013, an independent group of experts, known as the data and safety monitoring board (DSMB) found that the vaccine did not prevent HIV infection nor reduce viral load among vaccine recipients who became infected with HIV.

As a result, the DSMB recommended that no further vaccinations be given in the study and one day later on April 23, 2013 all vaccinations were stopped. All study participants, (vaccine and placebo recipients) were told these results, and will continue to be followed and counseled. A public announcement was made on April 25, 2013. Research and laboratory analysis will continue to try and understand why this result has occurred and to gather more information.

The HVTN 505 study enrolled 2,504 volunteers (men who have sex with men and transgender people who have sex with men) at 21 sites in 19 U.S. cities. The data examined by the DSMB was gathered from 1,250 people who received the investigational vaccine and 1,244 people who received the placebo vaccine. A series of 4 vaccines or 4 placebos were given over 6 months. In the primary analysis (which was based on those participants enrolled long enough to have received all vaccinations; 28 weeks or more) 27 HIV infections occurred among the vaccine recipients, and 21 HIV infections occurred among the placebo recipients. Overall, in the full group, including those who only recently entered the study and therefore received only a partial number of vaccines plus those with all vaccines, there were 30 HIV infections in the placebo group and 41 HIV infections in the experimental vaccine group. Through a series of analysis based on statistics and other mathematical models, it has been determined that while the number of HIV infections in the investigational vaccine group compared to those in the placebo group was somewhat higher, it is not statistically significant and the difference was due to chance. This will continue to be evaluated.

At this point, analysis has shown that all factors were equal between the two groups, such as HIV risk behaviors, the use of PrEP and Post-exposure prophylaxis, etc. While the use of PrEP/PEP was allowed by study participants, it was rare in this study (reported use about 3%).

HIV vaccine research and study leaders have commented: “The lack of effectiveness of the vaccine regimen in HVTN 505 is a setback to all who are dedicated to the mission of finding a safe and effective HIV vaccine. However, it is only through clinical research that we will ultimately achieve this goal. The trial participants continue to be our heroes. We must continue to move forward in the quest for an HIV vaccine.”

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