

THE HVTN 505 STUDY

ITS ROLE IN HELPING FIGHT HIV/AIDS

The world needs an HIV vaccine. We can't educate or treat ourselves out of the epidemic—we have to prevent new infections, and vaccines have historically been among the best tools in preventing infectious diseases. But HIV has proven itself to be a very challenging enemy, as shown by more than 20 years of HIV vaccine research. However, recent scientific findings show we are closer than ever to finding that elusive vaccine.

As of the summer of 2011, the HVTN 505 study has been expanded from 1,350 to enroll 2,200 HIV-negative men and transgender women who have sex with men.

By increasing the size of the trial, we will be able to answer the question of whether this vaccine regimen can reduce the number of new HIV infections, in addition to the original questions about whether the vaccine regimen can lower viral load among those who do become infected, and confirming that the vaccine is safe in the population being enrolled.

HVTN 505's RESEARCH OBJECTIVES

HVTN 505 is a study designed to answer three specific questions:

1 CAN THE VACCINE REGIMEN PROTECT AGAINST HIV INFECTION?

Our thinking about this vaccine regimen has changed and evolved as a result of recent developments in other HIV vaccine studies, and in monkey experiments with the monkey-equivalent vaccines. Since we now have data that were not available when we originally designed HVTN 505, there is good scientific justification to ask whether the vaccine regimen can reduce the likelihood of new infections.

2 CAN THIS VACCINE REGIMEN LOWER VIRAL LOAD AMONG PEOPLE WHO DO BECOME INFECTED?

Typically, the lower the viral load, the longer it may take before a person develops symptoms of AIDS. Having a lower viral load may also reduce the chances of passing the virus to others. A vaccine that could lower viral load might still have tremendous public health benefits, even if it could not prevent infection.

3 IS THE VACCINE REGIMEN SAFE AND WELL TOLERATED?

Safety is always a primary concern, and an objective of the study is to evaluate tolerability and safety in this population.

While this vaccine regimen is not on a path to licensure, the results of HVTN 505 will help us to better understand the human immune response to vaccines, and how to develop vaccines that are better able to produce the best immune response.



HIV VACCINE
TRIALS NETWORK

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SO, WHY NOW?

From a scientific perspective, it makes sense to evaluate the effect of this vaccine regimen on preventing HIV infection. It is the next logical step, given other recent advances in the prevention field:

- The Thai vaccine trial (RV144) results, announced in 2009, showed a modest but largely unexpected effect on preventing HIV infection—showing once again that we cannot predict the results of human vaccine trials.
- The Thai trial studied different vaccines than the vaccines in HVTN 505, but some of the immune responses seen to the vaccines in the Thai study were similar to some of the immune responses in other studies that tested the HVTN 505 vaccines.
- CAPRISA 004 and iPrEx have placed the idea of using anti-HIV drugs for prevention (not just treatment) in the spotlight. Both of these trials achieved moderate protection from HIV infection, and show the importance of evaluating prevention of HIV infection in human trials, wherever and whenever possible. Since combination approaches are emerging as an important area of HIV prevention research, we have made some changes to HVTN 505 to better understand how people view PrEP, and how it might work in combination with this vaccine regimen in those who voluntarily choose to take PrEP.

SAFETY FIRST

Safety is always our top priority and the design of HVTN 505 continues to reflect this. Key safety considerations built into this study include:

- The vaccines used in this study cannot cause HIV infection.
- For HVTN 505, we are limiting the study population to U.S. men who have sex with men (MSM) who are circumcised and do not have antibodies to Adenovirus type 5. In a previous study, men who fit these criteria and received the vaccine had the same rates of HIV infection as the men who received the placebo.
- The study continues to be monitored by the Data Safety Monitoring Board (DSMB). In addition to interim analyses of the data, the DSMB will review new infections as they are diagnosed to keep the closest possible watch on the study participants and their safety.
- All participants will receive the best available prevention services, including risk reduction assessment and counseling, condoms, and access to local prevention services.

THE LARGER HIV PREVENTION RESEARCH AGENDA

Hundreds of scientists around the world are working on finding a vaccine that will be safe and effective to prevent HIV/AIDS, but finding a vaccine is a long-term process that involves many studies, each designed to answer specific questions. Ultimately, as this larger effort generates and refines new vaccine candidates, they will need to be tested in many study volunteers, in populations around the globe. It will also be important to study how vaccines may work when used in combination with pre-exposure prophylaxis (PrEP), vaginal and rectal microbicides.



HOW YOU CAN HELP

The fight against HIV/AIDS is far from over. Millions of people are newly infected every year. A comprehensive program to fight this disease must include prevention, treatment and access to care. But as history demonstrates, a vaccine is our best long-term hope for ending this epidemic. There are many ways you can help in the effort to find a preventive vaccine:

VOLUNTEER FOR A RESEARCH STUDY

– Go to www.clinicaltrials.gov for the latest information on what trials are happening in your area. And if you are a man or transwoman who has sex with men, between the ages of 18-50, you can learn more about HVTN 505 at www.HopeTakesAction.org.

STAY CONNECTED

– Follow us on Facebook (www.facebook.com/helpendhiv) and Twitter (@helpendhiv).

BE INVOLVED

– Join an HVTN Community Advisory Board. Find the site nearest you at www.hvtn.org/about/sites.html.

GET TESTED

– Play safe and get regularly tested for HIV to help stop the spread of infection and make sure you get the care you need. Please visit www.hivtest.org to find an HIV testing center near you.