

Questions and answers: HVTN 082 vaccine trial

Version 1 – Last updated March 3, 2010

1. What is the HVTN 082 trial?

HVTN 082 is the name of a clinical trial to test the safety and immune response of 2 experimental HIV vaccines in twins. The study vaccines used in this trial are described in Question 4 below.

The products used in this trial are not produced from live HIV or from HIV-infected human cells. *These study vaccines cannot cause HIV infection.*

2. Who is conducting this trial?

This trial is sponsored by the Division of AIDS (DAIDS), within the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health (NIH), part of the US government.

The HIV Vaccine Trials Network (HVTN) will run the trial. The HVTN is an international collaboration of scientists, educators and community members searching for an effective and safe HIV vaccine. The HVTN is supported through a cooperative agreement with NIAID.

3. What is a vaccine trial?

A vaccine is given to people to prevent infection or fight disease. Currently there is no licensed vaccine against HIV. In order to develop an HIV vaccine, researchers need to test the study vaccines in humans. A vaccine trial is a way to test the safety of a vaccine and can also be used to find out if a vaccine might help prevent or fight HIV.

4. What kind of study vaccines are being tested in HVTN 082?

HVTN 082 tests 2 study vaccines called VRC-HIVDNA016-00-VP (DNA vaccine) and VRC-HIVADV014-00-VP (adenoviral vector vaccine) developed by the Dale and Betty Bumpers Vaccine Research Center (VRC), which is part of the US National Institutes of Health. None of the products used in this study can cause HIV or AIDS.

Both vaccines contain pieces of man-made HIV DNA. DNA is a natural substance found in all living things, including people and some viruses. DNA instructs cells to make proteins. When these study vaccines are injected, the DNA will tell the body to make small amounts of proteins that look like the ones found in HIV. This study will see if your body responds to the proteins.

One of the study vaccines (rAd5) is an “adenoviral vector” vaccine. It is made out of a certain kind of adenovirus. Adenoviruses cause colds, coughs, and diarrhea. A *vector* is a packaging system that can help deliver the vaccine into the correct part of the body or into the correct cell to create an immune response. The adenovirus in this study has been changed so that it cannot cause infections. The changed virus is used to deliver the man-made HIV DNA to the cells in your body.

5. Are these study vaccines safe?

Based on the data from animal and human studies, scientists believe that the study vaccines are suitable for use in human trials. The vaccines used in HVTN 082 have been used in more than 700 people in previous studies. However, there is always the possibility that there could be problems not one expected. That is why these study vaccines, like any new drug or vaccine, need to be tested in people in a clinic setting. Each participant's health and safety will be watched closely throughout the trial.

6. Can these study vaccines cause HIV infection?

It is *impossible* to get HIV infection or AIDS from these study vaccines. They are not made from live HIV, killed HIV, or HIV-infected cells.

These study vaccines cannot cause HIV infection.

7. How could the study vaccines help prevent HIV/AIDS?

As described in Question 4, the study vaccines contain pieces of manufactured DNA that look like pieces from HIV. There is no actual HIV in the vaccines. When the study vaccines are injected, the DNA tells the body to make proteins that look like HIV proteins. In responding to these proteins, a person's immune system may learn to recognize HIV without being exposed to actual HIV. An immune system that can recognize HIV through vaccination may be more able to fight the virus and to decrease the damage that HIV can do to the body, if exposure happens sometime later. However, it is not known if the vaccines will prevent HIV/AIDS. More clinical trials need to be done to learn if the vaccines can help prevent infection.

It is important to remember that being given a study vaccine does not mean a participant is protected from HIV infection. Participants are counseled on how to avoid behavior that will put them at risk of HIV infection.

8. Why is this trial being done?

The main purpose of the study is to learn more about how a person's genetic makeup shapes the way the immune system responds to vaccination. We know that a person's genes, passed down from his or her mother and father, may influence how a person might react to HIV vaccines. However, we do not know what this influence may look like. We are hoping to better understand the role of genetics by looking at the immune responses of twins to the HIV vaccines in this study. Knowing the answer to this question could help researchers design vaccines with greater potential to help fight HIV.

9. How many people are in this trial?

The trial will involve 80 twin pairs (160 participants total).

10. Who is eligible to participate in HVTN 082?

All participants must meet certain criteria to be eligible for the trial.

Participants must be healthy adults who are between 18 and 50 years old and HIV negative (free of HIV infection). Participants must have a twin sibling who is also eligible to participate in the study. Twins may be identical or fraternal.

Potential participants are asked about their medical history and are given a physical examination. They then have blood and urine samples taken for routine testing. They are also asked about their sexual activity and drug use. Those who are pregnant or breastfeeding are not eligible to participate in this trial.

11. When and where is this trial being conducted?

HVTN 082 will be conducted at multiple sites in the US. The trial is expected to begin enrolling participants around October 2009.

12. How will the safety and rights of participants be protected?

The HVTN works hard to protect the safety and rights of the participants. Before they join the trial, volunteers are given information about HIV and AIDS, about the reasons for the trial, about possible risks and benefits, and about trial procedures. The clinic staff allows plenty of time to talk with volunteers, answer their questions, and give information in writing.

After the trial has been fully explained, volunteers are asked to sign an informed consent form. They sign this form before being screened for eligibility and before enrolling. The informed consent form helps confirm that participants have made an informed decision about joining the trial. Volunteers will have plenty of time to think about whether they want to join the trial. They may decide not to enroll. If they do enroll, they may still leave the trial at any time without losing the benefits of their standard medical care.

During the trial, the clinic staff monitors participants to make sure the study vaccines are not causing them problems. Participants will be given any new information that could affect whether they want to stay in the study.

Participants are reminded often that being in a vaccine trial does not mean they are protected from HIV. They are counseled at every clinic visit on ways to avoid HIV. (This counseling might include, for example, talking about correct condom use.) It is important for participants to understand that any new study vaccine may have both medical and nonmedical risks.

13. Could the study vaccines cause a positive result on an HIV test?

Some study vaccines may make a trial participant test positive on an HIV antibody test, even if the participant is not infected with HIV.

One way vaccines can create an immune response is by causing the body to make antibodies. Antibodies are made by the body to fight infection. Common HIV tests look for antibodies against HIV. This means that after a participant gets a study HIV vaccine, a standard HIV test may say the person has HIV, even if that isn't the case. This result is called a "vaccine-induced positive" or "false-positive."

This clinic has special HIV tests that look for the virus itself instead of looking for antibodies. These tests can be used to determine if a positive test result is due to the vaccines or a true infection.

No health problems are associated with a positive HIV test result that is caused by a vaccine. But someone who gets that type of test result may be treated unfairly by others. People with a positive HIV test, even a vaccine-induced positive, are not allowed to donate blood. They may also have problems getting insurance or medical/dental care, traveling to other countries, obtaining employment, serving in the military or Peace Corps, or with their relationships with friends and family. The clinic staff can help with any such problems. Services exist to help any study participant with a vaccine-induced positive HIV test result.

14. How long will it take to obtain the results of this study?

It is hoped that the study will complete enrollment in 18 months. However, it may take two or more years until all of the results of the study are fully available. The results of HVTN 082 will help researchers better understand the immune system, and help them to design and test new HIV vaccines. Participants who received study vaccines in HVTN 082 will not be eligible for any future trial of these products.

15. Who reviewed and approved this trial?

The study vaccines are considered investigational, meaning the US FDA only allows them to be used in research. They have been made according to FDA guidelines and were reviewed by the FDA. The Protocol Team (the people who designed the trial) also carefully reviewed the information about the study vaccines before deciding to begin the trial.

The safety and rights of participants in HVTN 082 are monitored by Institutional Review Boards (IRBs) or Independent Ethics Committees (IECs) at each participating clinical research center. The safety of the trial is also monitored by local Institutional Biosafety Committees (IBCs). Community members are involved throughout the trial to ensure that the rights of participants are being protected and that their needs are being met.

16. For more information

About AIDS vaccine clinical trials: AIDS Clinical Trials Information Service, 1-800-TRIALS-A (USA only); www.clinicaltrials.gov

About the HIV Vaccine Trials Network: www.hvtn.org

If you have additional questions that were not answered by this document, please ask us.

You can contact: