



HIV VACCINE
TRIALS NETWORK

Frequently asked questions

HVTN 123 vaccine study

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1. What is a vaccine study?

A vaccine teaches the body to prevent a particular infection or fight a disease. In order to develop a vaccine, researchers need to test it in people. A vaccine study tests whether the vaccine is safe (does not cause health problems) and whether people's immune systems respond to the study vaccines. Your immune system protects you from disease. A vaccine study can also be used to find out if a vaccine might help prevent or fight an infection or disease. It takes many vaccine studies to produce a safe, effective vaccine.

Currently there is no licensed vaccine against HIV or AIDS.

2. What is the HVTN 123 study?

HVTN 123 tests 2 experimental vaccines against HIV. The study vaccines are called Stable CH505TF gp120 (gp120S) and Transient CH505TF gp120 (gp120T). From here on, we will call them **gp120S and gp120T study vaccines**. The study vaccines are supplied by the Division of AIDS (DAIDS) at the National Institutes of Health (NIH) in Bethesda, Maryland. The study vaccines are mixed with an adjuvant. An adjuvant is a substance that should help the immune system respond better to the vaccine. The adjuvant in this study is called GLA-SE and was made by the Infectious Disease Research Institute (IDRI) in Seattle, Washington.

The products used in this study are not made from live HIV, killed HIV, or HIV-infected human cells. These study vaccines cannot cause HIV infection or AIDS.

We can give you more detailed information about the study vaccines, if you would like.

3. What organizations are involved in this study?

DAIDS and the HIV Vaccine Trials Network (HVTN) developed this study, along with the company that made the study adjuvant, IDRI. DAIDS is part of NIH, which is part of the United States government.

The HVTN is an international collaboration of scientists, educators, and community members searching for an effective and safe HIV vaccine. The HVTN is funded by DAIDS.

Site: Add local site information about your organization, such as: "In Seattle, the study is taking place at the Seattle Vaccine Trials Unit, which is part of the Fred Hutchinson Cancer Research Center and the University of Washington."

4. When and where will this study be done?

Sites: Alter your site name as desired

The study is expected to begin enrolling participants around May 2019. It will be done in these locations: Atlanta, GA and Nashville, TN.

5. Why is this study being done?

All of the HVTN's studies work toward our mission to find a safe and effective HIV vaccine. The main purpose of this study is to see if the study vaccines are safe to give to people, and whether people are able to take the study vaccines without becoming too uncomfortable. Two other important goals of the study are to test if people's immune systems respond to the study vaccines and to see if the small difference in the way the 2 vaccines were made changes how people's immune systems respond.

6. How many people will be in this study, and who can join?

The study will involve 30 participants.

To join this study, a person must be healthy, between 18 and 50 years old, and not infected with HIV. They cannot be pregnant or breastfeeding. There are also other criteria that must be met. We will ask people about their medical history, give them a physical exam, and take blood and urine samples for testing. We will also ask people about their sexual activity and drug use.

7. Are these study vaccines safe?

We do not know all the risks of the study vaccines. The gp120S study vaccine has been given to about 42 people in another study that is ongoing. Although no one in the earlier study had any serious health problems related to the study vaccine, there is always the possibility that there could be problems no one expected.

The gp120T study vaccine has not been given to people before. Based on the results from studies of the gp120T study vaccine in animals, and the similarity between gp120S and gp120 T, researchers believe that the gp120T study vaccine is safe to give to people. However, results in animals do not always predict the results in people. That is why the main purpose of this study is to test whether the study vaccines are safe to give to people. Each participant's health will be watched closely throughout the study.

Both study vaccines will be given with an adjuvant, GLA-SE. GLA-SE has been tested in over 900 people with vaccines for other diseases. No one in these earlier studies had any serious health problems related to the adjuvant.

8. Can these study vaccines protect participants from getting infected with HIV?

Participants should not expect to be protected from HIV by these study vaccines.

This study is not designed to find out if the study vaccines work to prevent or fight HIV. More studies will need to be done to learn if they do.

Because it is not expected that the study vaccines will prevent HIV/AIDS, participants in this study will be counseled on how to avoid behavior that will put them at risk of HIV infection.

9. How will the health and rights of participants be protected?

Protecting the health and respecting the rights of participants are top priorities for everyone in the HVTN. Without volunteers, we would never be able to find an HIV vaccine.

A first step in protecting the rights of study participants is to give them information about the study before they join. Clinic staff will give people information about the study products and procedures, the possible risks and benefits to participants, and the rights that they have. These include the right to receive any new information about the study that could affect whether they want to stay in it, and the right to leave the study at any time.

During the study, the clinic staff will monitor participants to make sure the study vaccines are not causing any health problems. The clinic staff will also ask participants about any social problems they may experience from being in the study. If a participant has a health or social problem related to being in the study, clinic staff will help them.

There are also several groups involved in protecting participants' rights and well-being:

- A study safety review team and an independent safety monitoring board regularly look at the health information from the study to decide whether it appears safe to continue giving study injections.
- An Institutional Review Board (IRB) or Ethics Committee (EC) reviews and monitors the study plan for each clinic doing the study, including the information that is given to people about the study, study progress, and health problems in participants. The IRB/EC also looks at whether participant rights are being respected.
- The US Food & Drug Administration (FDA) also reviews the study. The FDA enforces US laws about research in humans and the use of study vaccines in research
- Each study clinic has a Community Advisory Board (CAB). Its members are local people who bring the concerns and interests of the community and study participants to the researchers. CAB members are part of the team that develops each study. They also help develop or review the information that is given to participants.

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

Yes, the study vaccines may cause you to test positive on some types of HIV tests. If a participant gets an HIV study vaccine, their body may make antibodies to HIV. Antibodies help you fight infection. Standard HIV tests search for HIV antibodies as a sign of infection. Because of this, a person could have a positive HIV test result even if they are not infected with HIV. This is called a vaccine-induced seropositive (VISP) test result. You may also see this called Vaccine-Induced Seroreactive. We do not know who will have VISP test results or how long these test results may last.

People with VISP test results need specific HIV tests to determine if a positive test result is due to VISP or a true infection. Clinics participating in this study have access to these specific tests that look for the virus itself instead of looking for antibodies.

No health problems are associated with a VISP test result, but VISP test results may cause problems in several areas such as medical or dental care, employment, insurance, a visa for traveling, or entry into the military. You might not be allowed to donate blood or other organs. If you are planning to apply for insurance, employment, or the military inform your study site right away. The insurance company, employer, or military agency may not accept HIV test results from the HVTN. However, the HVTN can work with them to ensure the right test is done that will show your true HIV status.

11. Where can I find more information?

About HIV vaccine clinical studies: www.clinicaltrials.gov

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

About VISP: <http://www.hvtn.org/en/participants/visp-hiv-testing.html>

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

You can contact: *Site: Add your contact information here.*



HIV VACCINE
T R I A L S N E T W O R K

HVTN 123 Vaccine Study: Additional Vaccine Information

The study vaccines are made from a protein that is similar to a protein found in HIV. (Proteins are natural substances. They help build and maintain your body, and do the same for viruses such as HIV.) This can also produce an immune response. An immune response prepares the body to recognize the same protein in HIV and fight the virus if a person is exposed to HIV in the future.