Frequently asked questions

HVTN 319 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 must create immune responses in order to prevent a disease. Researchers only need to test a vaccine in a small number of people to learn if the immune system responds to it. If a study vaccine produces the desired immune responses, this helps researchers decide whether to do more studies of the vaccine. 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 approved vaccine against HIV or AIDS.

1. What is the HVTN 319 study?

HVTN 319 tests 2 experimental vaccines against HIV. The study vaccines are called:

* UVAX-1107
* UVAX-1197

From here on, we will call them the “study vaccines.” The study vaccines were developed at the Scripps Research Institute and Uvax Bio and are being provided by Uvax Bio in Newark, Delaware, USA.

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

Both study vaccines are man-made to look like pieces of protein found on HIV. Proteins are natural substances. They help build and maintain the body, and do the same for viruses, such as HIV. The body’s immune system may respond to these proteins; this is called an immune response. An immune response prepares the body to recognize the same proteins in HIV and fight the virus if a person is exposed to HIV in the future. There are minor differences between the 2 study vaccines. Both study vaccines were made to start a strong immune response and make it more difficult for HIV to attach to your cells. We think that getting UVAX-1107 first will prepare your immune system to recognize the vaccine and start responding (this is called priming). This should help your body have a stronger response when you get UVAX-1197 (this is called boosting). Priming and boosting with vaccines is a common way to help the immune system have the best response.

In this study, both study vaccines are mixed with 2 study adjuvants. An adjuvant is a substance that should help the immune system respond better. The adjuvants in this study are 3M-052-AF combined with Alum. 3M-052-AF was developed by 3M Corporation, headquartered in St. Paul, Minnesota, USA. It is designed to stimulate parts of the immune system that recognize invaders like viruses. In this study, 3M-052-AF is being provided by the Access to Advanced Health Institute (AAHI) in Seattle, Washington, USA and will be combined with Alum. Alum is made from Aluminum Hydroxide. Alum is an adjuvant with a long-standing safety record that has been used in approved vaccines for more than 90 years. It will be provided by the Division of AIDS (DAIDS) at the US National Institutes of Health for this study.

1. Why are we giving the vaccine as a split dose in each deltoid muscle (upper arm) in this study?

The study vaccines will be split and given as two injections, one in each deltoid muscle (upper arm). This way, we may be able to better activate the lymph nodes, engage special immune cells called B cells, and lessen any local side effects.

1. What organizations are involved in this study?

The National Institute of Allergy and Infectious Diseases (NIAID) and the HIV Vaccine Trials Network (HVTN) developed this study, along with the companies that are supplying the study vaccines and adjuvants mentioned above. NIAID is part of the National Institutes of Health (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 NIAID.

 In Nashville, TN, the study is taking place at the HIV Vaccine Clinic at Vanderbilt University Medical Center

1. When and where will this study be done?

The study is expected to begin enrolling participants around May 2025. It will be done in these locations in the US:

Nashville, Tennessee at VUMC Medical Center

* University of Alabama- Birmingham, Alabama, US Birmingham
* Vanderbilt University, Nashville, Tennessee, US
* Physicians & Surgeons - Columbia University, New York, New York, US
* University of Rochester, Rochester, New York, US
1. Why is this study being done?

All of the HVTN’s studies work toward the mission to finding 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. Another important goal of the study is to test if people’s immune systems respond to the study vaccines.

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

The study will involve about 25 participants.

To join this study, a person must not have HIV, and must be healthy and between 18 and 55 years of age. Women 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.

1. Are the study vaccines safe?

We do not know all the risks of the study vaccines because they have only been given with different study adjuvants to about 33 people in another study. In that study, one participant had weakness and loss of feeling on the right side of their face 3 weeks after getting their third vaccine. This was eventually diagnosed as Bell’s Palsy. It was considered moderate in severity. The event was thought to possibly be connected to the study products (vaccines or placebo) because it happened shortly after receiving the treatment. We do not know for certain because the trial is still ongoing, and we do not know who got vaccines and who got placebo. This participant will not get any more vaccinations. As of November 19, 2024, the participant continues to recover with mild unevenness at the corner of the mouth and is still part of the trial for safety checks. UVAX-1107 and UVAX-1197 each combined with 3M-052-AF + Alum has not been given to people before.

So far, more than 200 people have received the study adjuvants 3M-052-AF + Alum with other study vaccines including more than 150 at the same dose that will be used in this study, and no one has had any serious health problems. In some of these studies, less than half of people had some combination of severe fatigue, body aches, and chills. Most of these side effects got better within 2-3 days, and all went away within 14 days. These side effects are also similar to what is seen with some approved vaccines.

Based on the results from studies of the vaccines in animals, researchers believe that the study vaccines combined with the study adjuvants seem 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.

1. Can these study vaccines protect participants from getting 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, participants in this study will be counseled on how to avoid behaviors that would increase their likelihood of getting HIV.

1. How long will it take to find out if the study vaccines work?

The results of HVTN 319 will help researchers to know if they should do more studies with these study vaccines. These additional studies would give the study vaccines to more people to see if they are safe. These studies would also give us a better understanding of how the immune system responds and whether the vaccines can prevent HIV acquisition. If more studies are done, it could take several years to find out if the study vaccines work. This study is expected to take a little less than 2 years to answer the research questions about safety and immune responses.

1. 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 and NIAID. 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 volunteers information about the study products and procedures, the possible risks and benefits to participants, and the rights that participants have. These rights include the right to receive any new information about the study that could affect whether a participant wants to remain in the study, 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 and 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). Each CAB’s 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.
1. 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 participant could have a positive HIV test result even if he or she does not have HIV. This is called a vaccine-induced seropositive (VISP) test result. You may also see this referred to as “vaccine-induced seroreactivity.” 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 having HIV. 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 of life, such as medical or dental care, employment, insurance, visas 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, please 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.

1. Where can I find more information?

About HIV vaccine clinical studies: [www.clinicaltrials.gov](http://www.clinicaltrials.gov)

About the HVTN: [www.hvtn.org](http://www.hvtn.org/)

About VISP: <https://www.hvtn.org/participate/visp-and-hiv-testing.html>

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

You can contact: *Shonda Sumner, MSN, RN, CCRP at 615-343-6906 or 661-886-8660.*