

NYU School of Medicine
Vaccine Study Frequently Asked Questions

1. Why is this study being done?

The MRKAd5 HIV-1 Trivalent vaccine is an experimental vaccine designed to prevent HIV infection. Previous research studies have already shown this vaccine to be safe, and an ongoing study is testing whether or not the vaccine lowers peoples' chances of getting infected with HIV.

The purpose of this study is to compare different dosages of the vaccine to look at how well people's immune systems respond to different dosage, also called "immunogenicity." This study wants to find out, if this vaccine is shown to work, what would be the best dosage to give. In this study different dose levels of the vaccine will be tested. The vaccine is made of an adenovirus (a virus that causes the common cold and sore throats) that has been changed to contain man-made copies of genes from HIV. When the vaccine is injected, it may cause your body to make proteins that look like they came from HIV. These proteins may help your body make an infection-fighting response against HIV. The vaccine does NOT contain live HIV. **You cannot get HIV infection or AIDS by receiving this vaccine.**

The study vaccine is investigational. This means the U.S. Food and Drug Administration (FDA) and other regulatory agencies will allow the experimental vaccine to be used only in carefully watched research studies.

2. Why should someone join this study?

Vaccines are studied in phases. This is a Phase IIb study. The purpose of this study is to find out the best amount of vaccine to create a strong immune response. Healthy volunteers are needed to make studies like this a success.

The contributions of healthy men and women are crucial to developing a safe and effective vaccine that could one day prevent HIV infection. The results of this study will tell us the best dose to use for a vaccine that may one day prevent HIV infection.

3. Who is running/sponsoring this study?

This study is sponsored by Merck & Co, Inc. NYU School of Medicine is one of the sites conducting the study for Merck & Co., Inc. Our clinic is located at Bellevue Hospital, 27th Street and 1st Avenue in Manhattan. If it is not convenient for you to do the study at our clinic, our study staff will assist you in finding another study site.

At NYU, the study is being conducted in our Center for AIDS Research. We have been conducting HIV treatment and preventive clinical trials for over 20 years.

NYU School of Medicine
Vaccine Study Frequently Asked Questions

Study staff at the NYU Center for AIDS Research:

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4. Who should participate in this study?

HIV-negative women and men, age 18-50, in good general health. Volunteers should be able to make the time commitment of 8 study visits over a 9 month period. There is no long term follow-up.

5. Who should not be in the study?

You should not be in the study if you have any of the following:

- Have had a positive test for HIV
- You know you are allergic to any part of the study vaccine or have any history of anaphylaxis (a severe allergy that can be deadly).
- Have received a blood transfusion or blood product in the past 3 months
- Have any history of cancer, with the exception of some kinds of skin cancer.
- Have a history of ongoing liver disease
- Weigh less than 105 lbs.
- Have participated in an HIV vaccine clinical trial in the past. NOTE: People who participated before in an HIV Vaccine clinical trial but who received only placebo may be eligible for the study.
- Are female and pregnant or breast-feeding, or expecting to get pregnant during the first 6 months of the study; or are male and planning to get a woman pregnant or provide sperm donation during the first 6 months of the study.

There may be other reasons why you cannot participate which will be discussed with you by the study staff.

6. What will I be asked to do? What are my requirements?

NYU School of Medicine

Vaccine Study Frequently Asked Questions

Before Entering the Study

To see if you can take part in this study, you will have two screening visits up to 45 days before vaccination. You will be asked questions about your medical history. You will have a complete physical examination. You will be asked about your sexual activities and recreational drug use.

You will have about 30 mL (about 2 tablespoons) of blood taken for safety tests and to check your immune system during these screening visits. These safety tests will see if your liver works normally. You will also be tested to see if you have been exposed to certain viruses like hepatitis, adenovirus, and HIV.

If you are a woman who is able to become pregnant, you will have a pregnancy test.

The study staff will use this information to decide whether you can take part in this study.

Being Assigned to a Group

This study will enroll about 204 volunteers total at over 20 different study sites. All study volunteers will receive the same experimental study vaccine at different dosages. They will be assigned by chance (randomly, like the toss of a coin) to receive one of three different dose levels at Day 1, Weeks 4 and 26. You and the study staff will not know the dose level you are receiving until the study is over, which may take a year or longer.

Vaccinations

Before each injection, women who are able to have children will have a pregnancy test. You will receive your first injection the day you enroll in the study and your next 2 injections at Week 4 and at Week 26. The vaccinations will be injected into your upper arm muscle.

After each vaccination, the clinical staff will observe you for 30 minutes to check for any possible side effects. It is important for you to report to the staff any side effects you have.

After each injection, you will receive a Vaccination Report Card (VRC). You will fill out the card every day for 14 days after you have been injected. You will write your daily temperature, any reactions that happen to you, and any medicines you take. You will be asked to bring your card with you your next study visit after each vaccination. The study staff will go over the information that you have written down.

NYU School of Medicine Vaccine Study Frequently Asked Questions

Clinic Visits

You will have about 8 clinic visits during this 9 month study, including the screening and injection visits. At each visit you will be asked how you are feeling. You will be asked if you are taking any medicines. Physical exams will be performed at some visits. You will be asked to give urine and blood samples. You will be tested for HIV before entering the study. You will be asked about your sexual activities and drug use at several visits. Safer sex counseling will be done at every visit.

If you are a woman who can become pregnant we will do up to 3 pregnancy tests as part of the routine study visits.

Blood Testing

We will draw about 2 tablespoons of blood at Visit 1, 1 tablespoon of blood at Visit 3, and about ½ cup of blood at Visits 4 and 6. Your blood will be used to measure your immune response to the vaccine to help determine what would be the best dose of the vaccine to give to others in the future. Your blood will also be used to test you for HIV and hepatitis.

7. **What is known about the study vaccine?**

The study vaccine in this study is made from adenovirus type 5, a virus that causes the common cold and sore throats. The adenovirus has been changed to contain man-made copies of three genes from HIV. It has also been changed so it cannot grow or cause colds and sore throats in people. Scientists call this kind of adenovirus “defective” or “weakened.”

When the study vaccine is injected, it may cause your body to make proteins that look like they came from HIV. These proteins may help your body make an infection-fighting response against HIV.

There is no possibility that the study vaccine can infect you with HIV.

The vaccines are not made directly from HIV, and they do not contain all the parts needed to make HIV. **You will never be injected with HIV during this study.**

The study vaccine has been tested in over 1300 people in the United States as well as over 700 people outside of the United States. The most common side effects that were experienced by people are described in detail below.

The study vaccine has also been studied in animals and has been generally well tolerated. Two other Adenovirus based HIV vaccines made by Merck & Co., Inc. that are like the study vaccine used in this study have been tested in

NYU School of Medicine Vaccine Study Frequently Asked Questions

over 450 other people in the United States as well as over 150 other people outside of the United States. People getting these other vaccines had very similar side effects to those getting the study vaccine.

8. How long will I be in the study?

You will be in the study about 9 months. You will complete a total of 8 visits in that time.

9. How many people will be participating in the study?

A total of 204 people at approximately 20 study sites will receive the MRKAd5 HIV-1 gag/pol/nef vaccine.

10. Will I be compensated for my time?

Volunteers will receive \$50 for each completed study visit. Volunteers will receive \$25 for each screening visit.

11. What side effects can happen to me by participating in this study?

Several studies have been done with this vaccine. In those studies people experienced similar side effects. The most common side effects were:

- Chills
- Diarrhea
- Dizziness
- Fatigue or feeling tired
- Headache
- Muscle aches and pains
- Pain, swelling or redness at the injection site
- Sore throat

Most of these side effects were mild and did not last more than a few days.

There is also the risk of you having an allergic reaction to the study vaccine components. Allergic reactions may include rash, hives, or even difficulty breathing and, in rare cases, anaphylaxis (a life-threatening, severe, whole-body allergic reaction).

12. Other Risks

Besides the possible adverse effects, other risks we know about are described below. There may be other side effects and risks to you (and to the

NYU School of Medicine

Vaccine Study Frequently Asked Questions

embryo or unborn child if you are or become pregnant) that are not presently known about study vaccine.

Adenovirus Vaccine Risk

The study vaccine is made from a weakened adenovirus. It has to be grown in special cells in the laboratory. One part of the special cell mixture is fetal calf serum, which is made from the blood of a baby cow. Any product made from a cow raises some concern about a rare but deadly brain disease called “variant Creutzfeldt-Jacob disease” (commonly known as “mad cow disease”). Special tests have been performed to check if the material that causes mad cow disease is in the study vaccine. These tests have not found this material in the study vaccine. We think that the risk of getting mad cow disease from the study vaccine is extremely small.

Pregnancy Risks

The effects of this study vaccine on an unborn child are not known. You must agree to use birth control during the 6 months of the study. Birth control is defined as oral or hormonal contraceptives, intrauterine devices (IUD), diaphragm with spermicide, condoms, or abstinence. If you are a woman who is able to have children, a sample of your urine will be tested for pregnancy just before each vaccination. If you are pregnant at the time of the first injection you will not be enrolled in this study. If you become pregnant during the study you will not get any more injections. The study personnel will stay in contact with you until the end of the pregnancy. If you become pregnant during the study, you must tell the study doctor immediately.

13. If you have an adverse effect, who will pay the doctor and hospital bills?

If you become sick or injured directly from the study vaccine, Merck & Co., Inc. will pay for the reasonable costs of medical treatment to the extent they are not covered by your medical or hospital insurance or by a third-party or government program providing such coverage. No other form of compensation is available. If you claim to have become sick or injured from participating in the study, Merck & Co., Inc. may give information that identifies you to its insurance carrier. This information will be used by the insurance carrier solely for the purpose of resolving your claim.

14. What benefit can I expect?

This study may be of no direct benefit to you. You will have the benefit of the study procedures (physical exam and laboratory tests). Science may benefit from the information derived from this study. The results of this study may help develop a vaccine that works for people throughout the world.

NYU School of Medicine
Vaccine Study Frequently Asked Questions

If the vaccine works, you may have some benefit. On the other hand, it may not work and there may be no benefit.

15. If I have more questions, or if I want to join the study, how do I contact you?

If you have questions about the study, call us at 212-263-0362, or e-mail us at prevention@gcrc.med.nyu.edu

If you are interested in participating in the study, please call 212-263-0362 to complete a telephone screen. Please note that all initial screenings must be conducted on the phone, not by e-mail.

Thank you for your interest in our research. We look forward to hearing from you.