

## **NYU School of Medicine Vaccine Study Frequently Asked Questions**

### **1. Why is this study being done?**

This is a Phase II proof of concept study of an experimental vaccine that may one day prevent HIV infection or keep people who do become HIV-infected healthier.

We are doing this study to answer 3 questions:

- Is it safe to give the study vaccine as an injection (shot) in a muscle?
- Does the study vaccine lower the chance of getting infected with HIV?
- If some people in this study get infected with HIV while the study is going on, does the study vaccine lower the levels of HIV in their blood?

The vaccine is made of an adenovirus (a common virus that causes colds 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-1. 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?**

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 may help develop a vaccine that works for people throughout the world.

### **3. Who is running/sponsoring this study?**

This study is sponsored by Merck & Co, Inc. in collaboration with U.S. National Institutes of Health (NIH), Division of AIDS (DAIDS), HIV Vaccine Trials Network (HVTN). NYU School of Medicine is one of the sites conducting the study for Merck & Co., Inc. Our clinic is located at Bellevue Hospital, 27<sup>th</sup> Street and 1<sup>st</sup> 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

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years. Most recently, we conducted a Phase I safety trial of this same vaccine. We have also conducted a Phase II safety trial and a Phase III efficacy trial of different preventive HIV vaccines.

Study staff at the NYU Center for AIDS Research:

Charles Gonzalez, M.D., Study Physician  
Robert Hagerty, Study Coordinator  
Gary Carlisle, R.N., Study Nurse  
Richard Silvera, Project Assistant  
Alith Maillard, Research Assistant  
Michael Marmor, Ph.D., Principal Investigator

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Website: [www.HIVInfoSource.org/vaccine2005](http://www.HIVInfoSource.org/vaccine2005) and click on "Merck 023"

E-mail: [HIVvaccine@gcrc.med.nyu.edu](mailto:HIVvaccine@gcrc.med.nyu.edu)

### **4. Who should participate in this study?**

HIV-negative women and men, age 18-45, in good general health. Volunteers should be able to make the significant time commitment of 15 study visits: 1 screening visit before joining the study, 7 visits in the first year, and 7 follow-up visits over the next 4 years.

### **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 been vaccinated with a live virus vaccine, (e.g. Chickenpox vaccine) within 30 days before getting the first dose of vaccine/placebo or scheduled within 14 days after.
- Have or think you might have a problem with your immune system such as autoimmune disease, splenectomy, or diabetes mellitus.
- Have any history of cancer, with the exception of some kinds of skin cancer.
- Have received an experimental HIV vaccine in the past.  
NOTE: People who have already participated in an HIV Vaccine clinical trial but who received only placebo may be eligible with documentation.

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- Are female and pregnant or breast-feeding, or expecting to get pregnant during the first 30 weeks of the study; or are male and planning to get a woman pregnant or provide sperm donation during the first 30 weeks 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?**

#### Before Entering the Study

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

You will have about 30 mL (about 2 tablespoons) of blood taken to check 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

1500 volunteers in North America, South America, the Caribbean, and Australia will be enrolled in the study.

You will be assigned by chance (randomly, like the toss of a coin) to receive Study Vaccine or placebo. There is an equal chance of you getting the Study Vaccine or the placebo if you join this study.

You and the study staff will not know if you are receiving vaccine or placebo. In an emergency, this information can be made available to the study staff (a process called “unblinding”).

#### Vaccinations

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

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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 side-effects you may experience, and any medicines you take. Bring your card with you to each of your study visits after each vaccination. The study staff will go over the information that you have written down. You will return the completed card to the study staff after 14 days.

#### Clinic Visits

You will have about 15 clinic visits during this 4 year 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 have to give urine and blood samples. Your blood sample will be tested for HIV before entering the study and at least 10 more times during 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. We, or you, may also request additional HIV or pregnancy tests.

You will be asked to visit the study clinic about 9 times during the first 1 ½ years of the study. After that, you will be asked to visit the study clinic 6 more times, once every 6 months for the last 3 years of the study. At each of these 6 visits a medical history will be taken and blood will be drawn for HIV testing.

#### Blood Testing

At some of your visits, we will draw about 5 mL up to the maximum of 115 mL (about 1 teaspoon to less than a half cup) of blood. Your blood will be used to test the safety of the vaccine with routine tests. If any of the tests are abnormal, additional blood may be required for further testing. If there is a problem at any time with any of the safety blood or urine tests, your study doctor or nurse will discuss them with you. Some of your blood will be used to measure your immune response to the vaccine.

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

The MRKAd5 HIV-1 gag/pol/nef vaccine has been given to over 150 people so far. A similar vaccine, the MRKAd-5 HIV-1 gag vaccine, has been given

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to over 450 volunteers in the United States. Volunteers have received two doses of this vaccine at three different dose levels or placebo. In other studies another similar gag vaccine, the Ad5 HIV-1 gag, has been given to over 200 volunteers in the United States. They have received one to three doses at four different dose levels or placebo. Side effects from the MRKAd-5 HIV-1 gag vaccine are listed in listed in the “Potential Risks and Discomforts” section.

### **8. How long will I be in the study?**

You will be in the study about 4 years. You will complete a total of 15 visits over those 4 years: 1 screening visit, 7 visits in the first 1 ½ years of the study, and 7 visits in the remaining 3 ½ years of the study.

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

A total of 1500 people at more than 20 study sites will receive the MRKAd5 HIV-1 gag/pol/nef Vaccine or placebo in this study.

### **10. Will I be compensated for my time?**

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

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

Some people have reported temporary moderate to severe side effects in the first 24 to 48 hours after receiving the vaccine. These side effects included fevers, chills, tiredness, and muscle or body aches. Some people who had these temporary side effects also showed temporary lower white blood cell count; most returned to normal within a week of injection.

There may be some discomfort from the vaccination. The following are some ways discomfort can occur:

- An allergic reaction to the vaccine—rash, hives, or even difficulty breathing can occur.
- Injection site reactions such as soreness, bruising, pain, redness, swelling, itching, rash, and stiffness can happen with any vaccination.
- Other reactions known to occur with vaccines in common use include fatigue, chills, aches, headache, loss of appetite, nausea, vomiting and diarrhea.

Below are the more common side effects in the ongoing studies using the MRKAd5 HIV-1 gag vaccine. The exact number of volunteers who experience these side effects will not be known until these studies are

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completed. In addition, it is unknown if volunteers who have experienced side effects received placebo or vaccine. In an ongoing study in healthy people side effects included:

- Fever
- Headache
- Fatigue or feeling tired
- Chills
- Muscle aches or weakness
- Nausea and vomiting
- Diarrhea
- Other aches and pains
- Difficulty sleeping
- Cough
- Sore throat
- Runny nose or stuffy nose (sinus congestion)
- Dizziness

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

##### Adenovirus Vaccine Risk

The cells used to make the adenovirus vaccine came from human fetus eye cells. The cells were grown in the laboratory with fetal calf (animal) serum. Serum is made from blood and is often used to help grow different cells.

There is a theoretical risk that the organism that causes variant Creutzfeldt-Jacob disease (Mad Cow Disease), a deadly brain disease, could have been present in the serum and could still be present in the adenovirus vaccine. To the extent that is practical, precautions have been taken to reduce the risk. The risk has been estimated to be very low. The FDA has established strict serum preparation guidelines to prevent this from happening. We have followed these and all other guidelines carefully. The risk is not absolutely zero but—just to give you an idea—it is much less than the chance of being struck by lightning.

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Pregnancy Risks

The effects of this study vaccine on an unborn child are not known. You must agree to use birth control during the first year of the study and should not donate eggs or sperm until at least 3 months after the last injection. 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 get 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.

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

Also, you may have received placebo vaccine that does not contain any active ingredient, in which case you would not 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 [HIVvaccine@gcrc.med.nyu.edu](mailto:HIVvaccine@gcrc.med.nyu.edu)

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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.