



HIV VACCINE TRIALS NETWORK

Questions and answers for participants: HVTN 087 vaccine trial

Version 1 – Last updated January 5, 2015

1. What was the purpose of this study?

The purpose of the study was to test the safety of the experimental vaccines and the study adjuvant. We also wanted to see if people would be able to have electroporation with study products without becoming too uncomfortable. The study also tested how people's immune systems respond to the study products. (Your immune system protects you from disease.) Lastly, we wanted to see if different doses of the adjuvant affected the immune response.

2. How many people were enrolled in this study and what product(s) did the people receive?

A total of 100 people participated in this study: There were 65 men and 35 women. The first person joined the study on May 21, 2012. The last person joined the study on June 17, 2013. Twelve people received placebo. Sixty-six people received the HIV-MAG vaccine with the adjuvant and 22 people received the HIV-MAG vaccine without the study adjuvant. Seventy-five people also received the VSV vaccine. Overall, 72 people (72%) received all of their 4 scheduled injections. A total of 92 people (92%) came to their final study visit.

3. What has been learned from the study?

We learned that people are able to take the HIV-MAG study vaccine and adjuvant by electroporation, and VSV by needle and syringe, without being too uncomfortable. Most side effects were mild or moderate reactions that happened in the first few days after vaccination. These side effects included pain or tenderness, tiredness, feeling unwell, fever, chills, headaches, nausea and body aches. Fifteen participants reported that some of these symptoms were severe enough to interfere with normal daily activities or cause the participant to miss work for a day. These reactions did not last long and the people who had them recovered without any problems. Many of these side effects are often seen in vaccine trials, and also with licensed, commercially available vaccines. About 40 participants had blood counts done at 1 and 3 days after VSV vaccination. Fifteen of these participants had low counts of white blood cells, called lymphocytes, one day after the VSV vaccine, but the counts quickly returned to normal by day 3, and did not cause any problems.

4. How do the results from this study fit into the bigger picture of HIV vaccines?

The results from this study are consistent with results from other HIV vaccine trials of similar DNA and viral vaccines, which show that the study products work well together to produce immune responses against HIV. Additional work is needed to improve the vaccines, and so these vaccines and others will continue to be tested..

5. Will there be any future testing of these study products by the HVTN?

Yes. The study products are expected to continue into another study next year (2015). A second VSV vaccine will be added to increase immune responses.

6. Will the study vaccine(s) protect me against HIV infection?

Based on the results of this study, and information from other studies, we would not expect these study vaccines to prevent HIV infection. You should continue to avoid exposure to HIV.

7. Will the study vaccine(s) affect my HIV test results in the future?

At the end of the study, we tested you using several common antibody tests for HIV. If you received a positive test result caused by the vaccine, you will be provided with free HIV testing for as long as you need it. We use tests that will tell the difference between a real infection and a reaction to the study vaccine. If you tested negative for HIV at the end of the study, you can go elsewhere for your HIV testing in the future. Although it is unlikely, if you received the study vaccine, you might have a negative test result at the end of the study and later receive a positive test result caused by the vaccine(s). This could happen if more sensitive HIV antibody tests are developed. While this situation is rare, if you are concerned, you can talk to the study staff before or after you get an HIV antibody test outside of this study site.

If you received study vaccines and tested antibody-positive at any time, we can provide free testing for HIV for as long as you need it. If this happens, we do not know how long you will stay antibody-positive due to the study vaccines.

8. Can I participate in another HIV vaccine trial?

We have told you which product(s) you received.

If you received the study vaccine(s), you probably cannot participate in another HIV vaccine trial. This is because it might be hard to measure how your system responds to a vaccine in another trial. However, there may be other HVTN trials that you could join.

If you received a placebo, you may participate in another HIV vaccine trial. If you are interested in doing this, we can tell you if there are other HIV vaccine trials being done at this clinic.

9. Who should I contact if I have questions or problems?

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

You can contact: