HIV VACCINE TRIALS NETWORK

HPTN HIV Prevention Trials Network

Questions and answers for participants: HVTN 140/HPTN 101

1. What was the purpose of this study?

The HIV Vaccine Trials Network (HVTN) and the HIV Prevention Trials Network (HPTN) did this study to test a combination of different antibodies against HIV. HIV is the virus that causes AIDS. Antibodies are one of the ways the human body fights infection. Antibodies are natural proteins that the body can make to prevent infectious agents such as bacteria and viruses from making you sick. Researchers can also make antibodies in laboratories. Antibodies can be given to people in a vein (by intravenous infusion, called IV) or under the skin (by subcutaneous infusion, called SC).

HVTN 140/HPTN 101 tested three antibodies against HIV. The antibodies are called PGDM1400LS, PGT121.414.LS and VRC07-523LS. There were 2 parts of this study, Part A and Part B. In Part A, participants were given different doses of one of the study antibodies, PGDM1400LS, by IV or SC infusion. We wanted to understand if this study antibody is safe to give to people and whether people are able to take this antibody without becoming too uncomfortable. We also looked at whether the method of giving this antibody changed the way the body responds, and how much of this antibody remained in the body over time. Participants were followed in Part A for approximately 6 months.

In Part B, participants were given a combination of all three study antibodies by IV or SC infusions, scheduled on the first day and 4 months later. We wanted to understand if the combination of study antibodies is safe to give to people and whether people could receive the combination without being too uncomfortable. We also looked at whether the method of giving the antibodies changed the way the body responds, and how much of the antibodies remained in the body over time. Participants were followed in Part B for approximately 10 months.

2. Who joined this study?

A total of 95 people participated in this study:

- 48 (51%) were assigned female sex at birth
- 47 (49%) were assigned male sex at birth
- 46 (48%) identified as female
- 46 (48%) identified as male
- 0 identified as transgender
- 3 (4%) identified as having another gender identity
- 26 (27%) were White
- 50 (53%) were Black/African American
- 1 (3%) was Native American/Alaska Native

- 15 (16%) was Multiracial
- 1 (1%) were Asian
- 3 (3%) were Other
- 6 (6%) were Hispanic/Latino

Participants ranged in age from 18-48 years of age, with an average age of 27 years.

Participants did not have HIV and were assessed as having a low likelihood for acquiring HIV. In total, 73% of participants described their sexual orientation as heterosexual, 12% as homosexual, 11% as bisexual, and 5% reported that they had another or unknown sexual orientation.

The first person joined the study on November 15, 2021. Enrollment of 15 participants in Part A was completed on March 4, 2022. Enrollment of an additional 80 participants in Part B began on March 16, 2022, and was completed on October 5, 2022 (total enrollment of 95 participants for the study). The last study visit was completed on July 19, 2023. Approximately 95% of the participants remained in the study through the final visit.

Overall, 15 people (100%) completed all of the scheduled infusions in Part A and 71 out of 80 people enrolled (89%) completed all of the scheduled infusions in Part B. Here are the reasons that the 9 participants did not complete all the infusions:

- Four participants did not get the last scheduled infusion because they had stronger side effects after getting the previous infusions.
- One participant declined further infusions due to a medical condition that was not related to the study products.
- Four participants were not able to adhere to the visit schedule.

3. From what locations were participants enrolled?

- Atlanta, Georgia, United States
- Nashville, Tennessee, United States
- Newark, New Jersey, United States
- San Francisco, California, United States
- Washington, DC, United States
- Cape Town, Western Cape, South Africa
- Durban, KwaZulu–Natal, South Africa
- Johannesburg, Gauteng, South Africa
- Harare, Harare Province, Zimbabwe
- Kericho, Kericho County, Kenya

4. What has been learned from the study?

We learned that most people are able to receive the study antibodies without becoming too uncomfortable. Most side effects were mild to moderate that happened in the first few days after the infusions. These side effects included pain or tenderness at the site where they got the infusion, tiredness, feeling unwell, headaches, and body aches.

In Part A, 3 participants reported that some of these symptoms were severe enough to interfere with normal daily activities. One participant reported a severe rash at the site where the infusion was given that started 7 days after SC study product administration. One participant who got IV infusions reported a moderate headache, and 1 participant had moderate redness and swelling at the site where the SC infusion was given.

In Part B, 4 participants who got SC infusions had a severe reaction of redness and swelling at the site where the infusion was given.

The 7 participants in the study who had these reactions recovered and did not require any further treatment. These side effects are often seen in vaccine and antibody studies, and also with approved vaccines and antibodies.

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

We are still analyzing the collected blood samples for antibody levels in participants' blood. This study confirmed that these antibodies are safe and well tolerated overall. In addition, this trial showed that it may be good to use these study antibodies in future studies looking at combinations of antibodies given to people to prevent HIV. Data from this study will help make decisions on how much and how often to give these antibodies in future studies.

6. Will there be any future testing of these study products by the HVTN/HPTN?

Yes, these study antibodies are now being tested in combination with other antibodies against HIV in early-stage studies and may be considered for future studies.

7. Will the study antibodies protect me from acquiring HIV?

We do not know if the study antibodies can prevent you from acquiring HIV as this study was not designed to answer that question. You should continue to take steps to reduce your chances for acquiring HIV.

8. Will the study antibodies affect my HIV test results in the future?

The study antibodies should not affect your HIV antibody test results now or in the future. The study antibodies were last given to participants on February 2, 2023. We do not expect the study antibodies to still be present in people's bodies now, more than a year later.

9. Can I participate in another HIV vaccine or antibody study?

Maybe, but it will depend on the study. If you are interested in joining another HIV antibody or vaccine study, the study doctor will assess if you are eligible to participate.

10. 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: Dr Carrie-Anne Mathew
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