

The **VOICE** Study



Many People Are Getting HIV/AIDS



Since there is no cure, studies are being done to find ways to prevent getting HIV/AIDS.

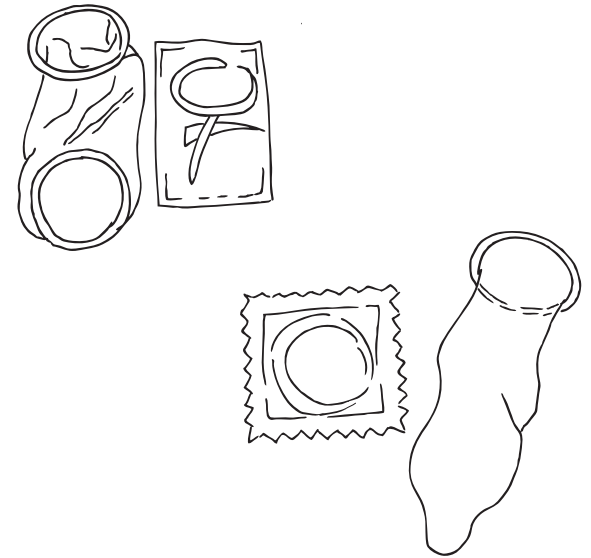
We Know There Are 3 Ways Women Can Prevent Getting HIV Through Sex



1. Not having sex



2. You and your partner only having sex with each other, if both of you do not have HIV



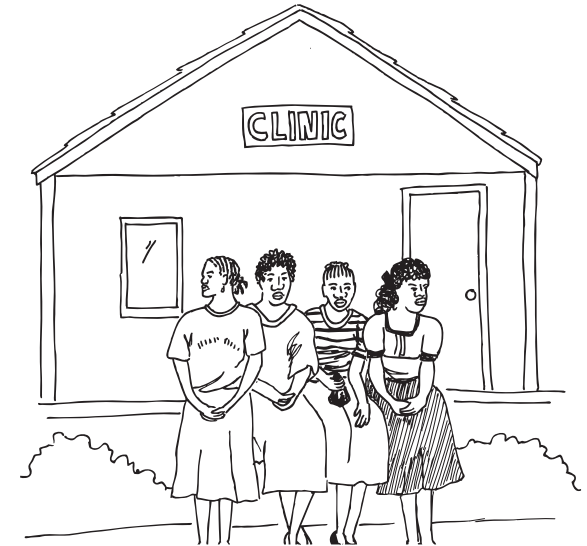
3. Using a condom correctly every time you have sex

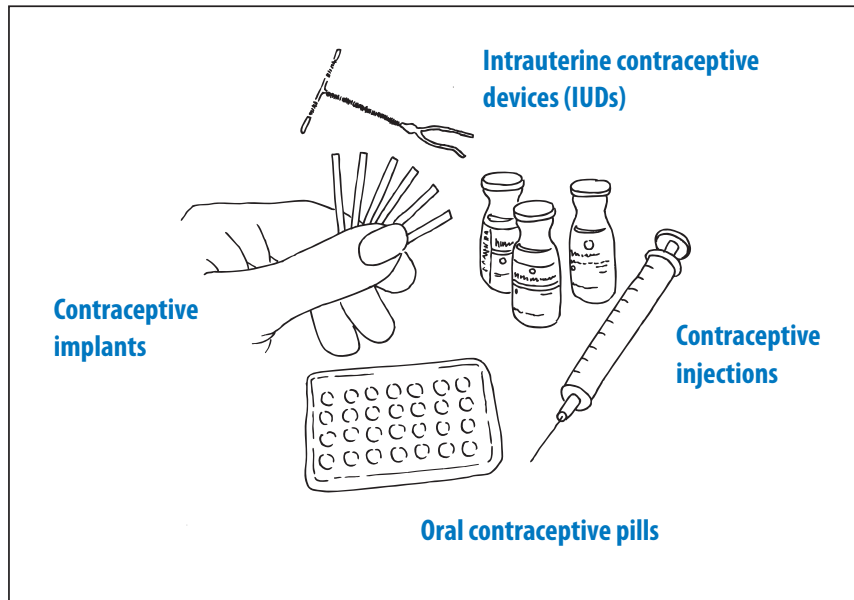
Something New May Help Prevent Getting HIV



There are many steps to finding products that will work. First, small studies are done on animals, and then small groups of people, to test if the products are safe to use. Next, larger studies, with many more people, are done to test if the products prevent getting HIV.

Studies are being done to test if gels inserted in the vagina, or tablets taken by mouth, may prevent getting HIV. As of today, no gels or tablets have been shown to prevent getting HIV, but researchers are trying to find products that will work.



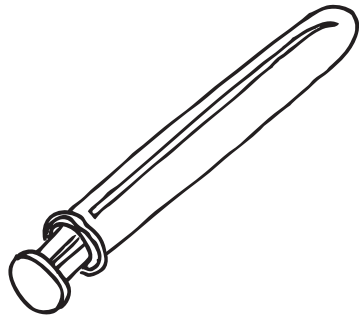


You probably know about family planning methods used to prevent pregnancy. It took many research studies to find methods that prevent pregnancy, and many women took part in these family planning research studies.

The staff here would like to tell you about a research study being done to try to find ways to prevent women from getting HIV. This research study is called the VOICE Study (Vaginal and Oral Interventions to Control the Epidemic).



The researchers here are doing this research study to test a vaginal gel and two different tablets.



The gel is called **Tenofovir gel**.



The tablets are called **Tenofovir tablets** and **Truvada tablets**.

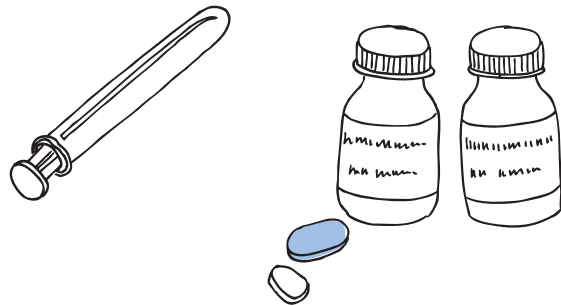


Tenofovir and Truvada are antiretrovirals (ARVs), which are medicines used to treat HIV/AIDS. This research study will test if these medicines, in the form of a gel or tablet, prevent women from getting HIV. Tenofovir and Truvada work well with other medicines to **treat** HIV/AIDS, but we do not know if they work to **prevent** getting HIV. This research study is being done to find that out.

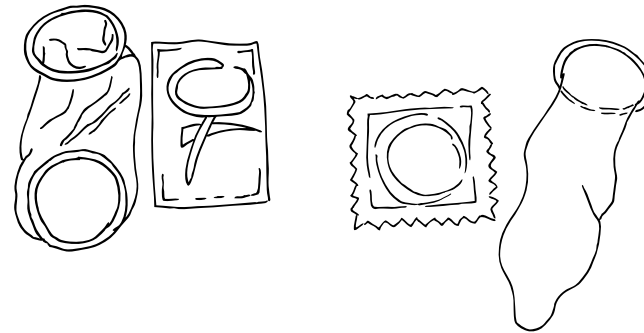
Thousands of women from 5 African countries — Malawi, South Africa, Uganda, Zambia, and Zimbabwe — will take part in this research study. You may be eligible to join this research study. This booklet gives you information to help you decide whether to join the research study.

About The Research Study

This research study is testing Tenofovir gel, Tenofovir tablets, and Truvada tablets.

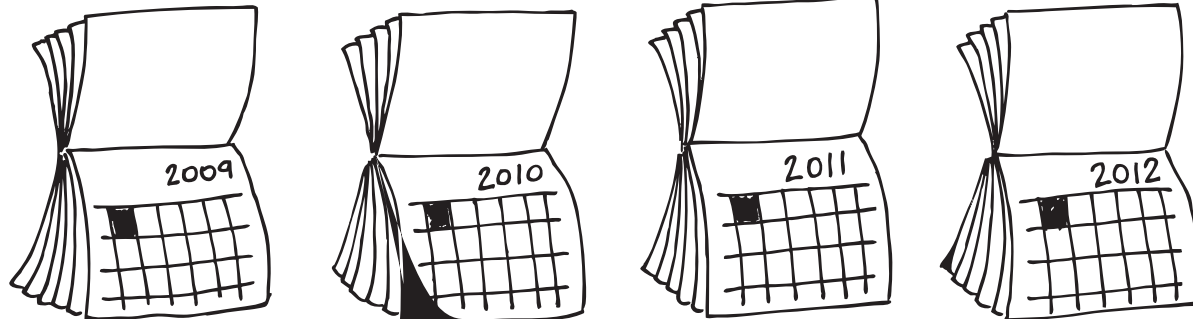


Because we do not know whether Tenofovir and Truvada prevent getting HIV, women in the study need to use condoms every time they have sex to prevent getting HIV.

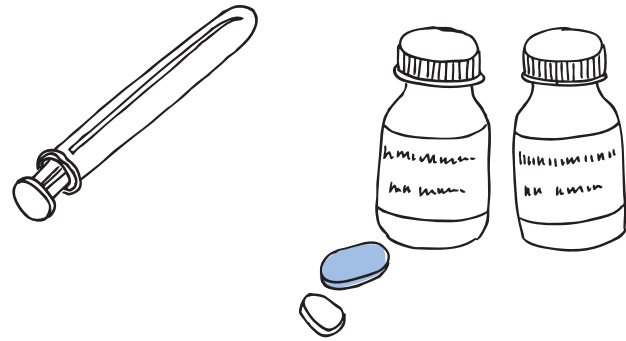


The study will take about 4 years, from the time the first woman joins to the time the researchers have the study results. **Each woman will be in the research study for 1-3 years, depending on when she joins.**

BEGIN



END



Some women will be given a gel to insert in the vagina, once each day, every day, while in the research study. Other women will be given tablets to take by mouth, once each day, every day, while in the research study. Women will need to take the gel or tablets every day, **even if they do not have sex.**

Women will be tested for pregnancy, HIV, and other infections passed during sex (STIs). The pregnancy tests are needed because the gel and tablets have not been tested in pregnant or breastfeeding women. **Women who are pregnant, breastfeeding, or want to become pregnant in the next 2 years should not join the research study. Women who join the research study must agree to use reliable family planning.**

Intrauterine contraceptive devices (IUDs)



Contraceptive implants

Contraceptive injections

Oral contraceptive pills

Study Groups

There are 5 groups of women in the research study. Depending on their group, women will either be given gel or tablets to use every day. Two (2) groups will be given a gel. Three (3) groups will be given tablets. All groups will be given condoms and counseled to use condoms to prevent getting HIV. More information about the 5 groups is given below.



Study Groups

To test Tenofovir gel, 2 groups are given a gel to insert in the vagina every day. One of these groups is given Tenofovir gel. The other group is given placebo gel. Placebo gel looks and feels like Tenofovir gel but does not contain Tenofovir or any other active ingredient.



The 2 gel groups are:

- Tenofovir gel
- Placebo gel

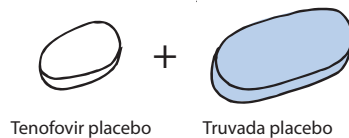
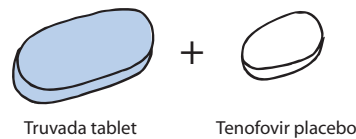
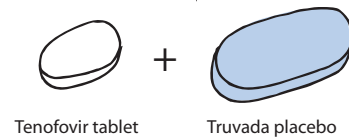


Study Groups

To test Tenofovir and Truvada tablets, 3 groups of women are given tablets to take by mouth every day. One of these groups is given Tenofovir tablets plus a placebo tablet. The second group is given Truvada tablets plus a placebo tablet. The third group is given two placebo tablets. Placebo tablets look like Tenofovir and Truvada tablets but do not contain any Tenofovir or Truvada or any other active ingredient.

The 3 tablet groups are:

- Tenofovir tablet + placebo tablet
- Truvada tablet + placebo tablet
- Placebo tablet + placebo tablet

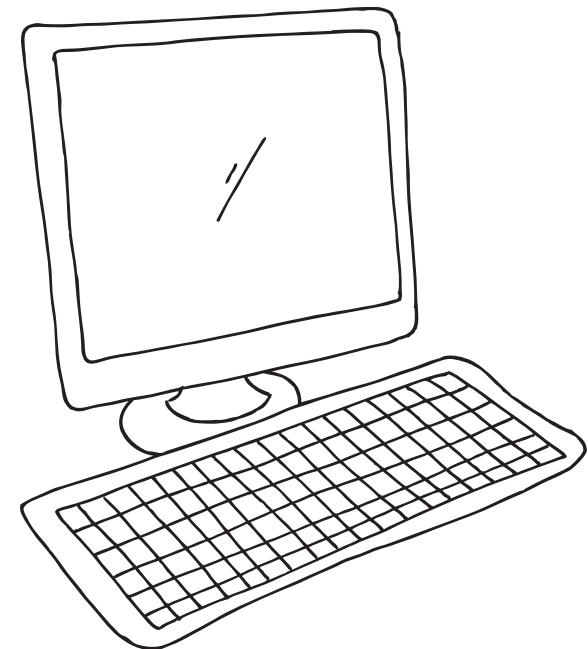


Study Groups

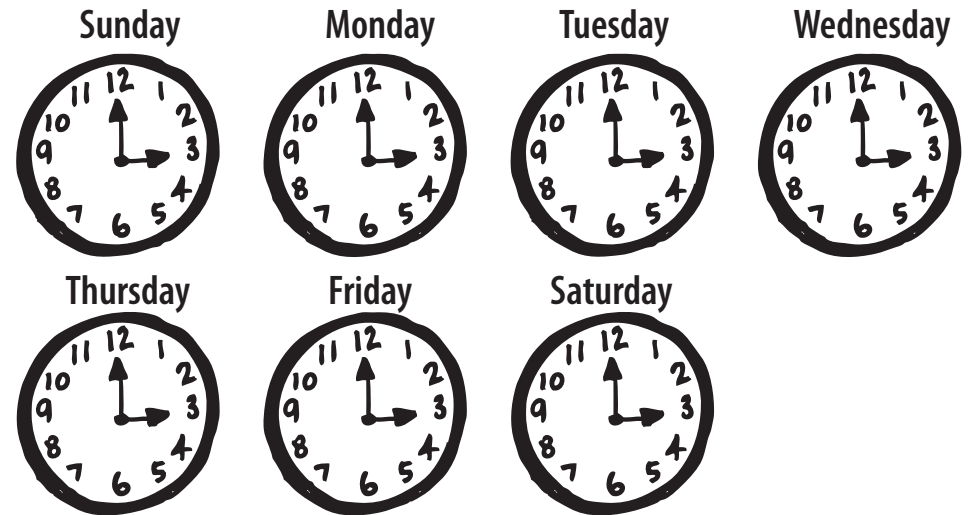
You may wonder why some women are given Tenofovir gel, Tenofovir tablets, or Truvada tablets, while others are given placebo gel or placebo tablets. The placebo gel and placebo tablets are needed to help researchers understand the effects of Tenofovir and Truvada. No one will know which women are using Tenofovir or Truvada, and which are using placebo, until the study is finished. The researchers will then compare the women who used Tenofovir or Truvada to the women who used placebo to find out if the Tenofovir or Truvada prevented women from getting HIV.

All women have an equal chance of being placed into one of the 5 groups.

The group each woman is placed in is chosen by a computer. The way each woman's group is chosen is by chance, like throwing dice or flipping a coin. The study staff cannot choose the group for any woman. No woman can choose her group for herself. Once a woman is placed in a group, she must accept the gel or tablets of that group. She cannot change her group.

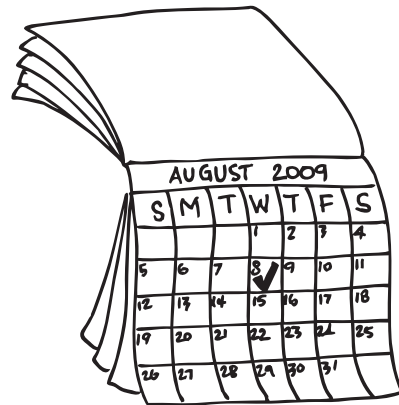
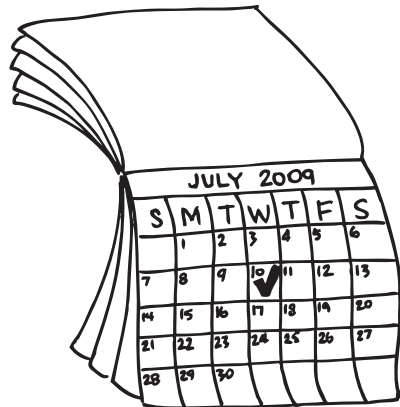


To properly test if the gel or tablets prevent getting HIV, it is very important that women in the study use the gel or tablets they are given, every day. Women should also use their gel or tablets around the same time every day.



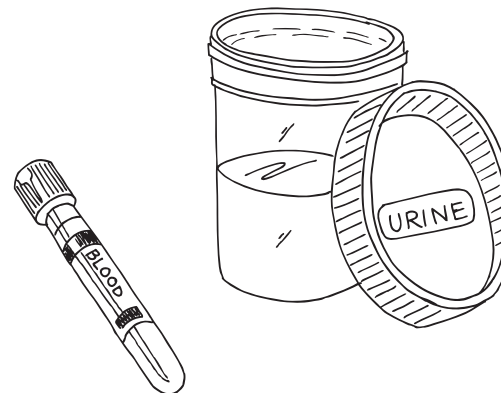
Study Visits

Women in the study will visit the clinic every month.



At each visit they will:

- Answer questions about their health and sexual behaviors
- Answer questions about their use of gel or tablets
- Have a urine test for pregnancy
- Have a blood test for HIV
- Discuss ways to prevent getting HIV
- Be given condoms



Study Visits

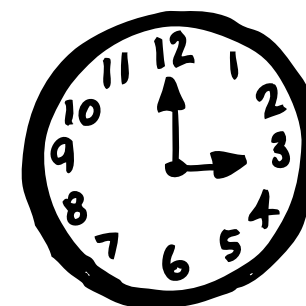


At some visits, women will have an examination of their body. Some examinations will include the genital area and inside the vagina. Women will also have blood and urine tests to check their health and if they have STIs.



If women get an STI, they will be counseled and treated. Their partner(s) can come to the clinic for treatment too.

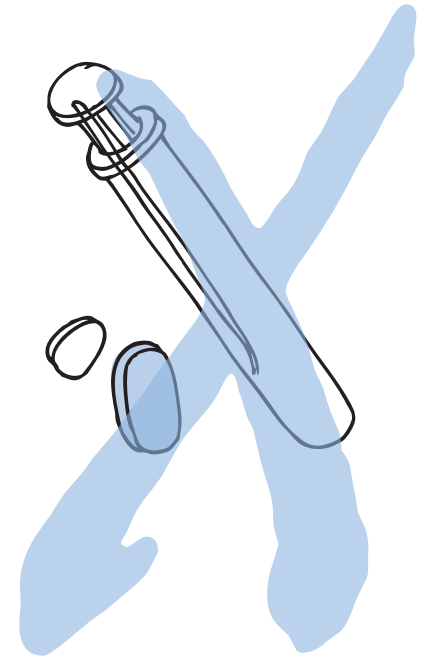
Visits to the clinic will take time, so women need to plan for this. Women will be reimbursed for their transport and time for scheduled visits.



Women should not get pregnant while in this research study. But if they do, they will stay in the study and will be referred for antenatal care. They will stop using gel or tablets while pregnant or breastfeeding.

If women get HIV, they will stay in the research study and be counseled and referred for care they may need. They will stop using gel or tablets.

Women may also stop using gel or tablets due to other health problems. Even if a woman stops using gel or tablets, she will stay in the research study.



Risks



The gel and tablets could cause problems. Women who use gel may have pain, itching, or discomfort in the genital area. Women who use tablets may have headaches, body pain, body weakness, rash, fever, nausea, diarrhea, or dizziness. They may have problems with their kidneys, liver, and bones. The gel and tablets could cause other problems we do not know about. **Women must tell the study staff about any health problems, so they can be helped.**



Some women do not like answering questions or having blood tests or physical examinations. Some women may become embarrassed or worried. The study staff will counsel women about any concerns.



Sometimes women in a research study feel that others are spreading rumors about them or treating them unfairly. The study staff will try their best to stop this.

Some women may get HIV while using gel or tablets. If these women use Tenofovir or Truvada after getting HIV, Tenofovir and Truvada may not work for them as treatment for HIV/AIDS. For this reason, women are tested for HIV at every visit and must stop using gel or tablets if they get HIV.

For this same reason, women must never share or sell their gel or tablets with anyone else. If other people who have HIV use the gel or tablets, Tenofovir and Truvada may not work for them as treatment for HIV/AIDS.



Benefits



Women may feel some satisfaction from helping to find ways to prevent getting HIV. We hope the study gel or tablets can help, but we cannot know if they work until the research study is finished.



Women will learn about their health. They will have tests and examinations. They will get condoms and counseling on how to prevent getting HIV and STIs. They will receive treatment for STIs and referrals for treatment of other illnesses. Partners can get HIV counseling and testing and STI treatment.



Voluntary And Confidential

Deciding to join a research study is an individual choice.

You may ask questions to help you decide whether to join this research study. Please continue to ask questions at any time.

If you decide not to join this research study, it will not affect your health care. You may join other studies in the future if you are eligible.



If you join this research study, the study staff must keep all information about you confidential. They will keep your information locked away where no one else can see it.

If you join this research study, you cannot also take part in other research studies. This is very important for your safety. This also is important because if you join other research studies, researchers will not be able to understand if the gel and tablets being tested in this study are safe and work to prevent HIV. Study staff will check with other research clinics to ensure you are not in other studies. Please tell the study staff if you are in any research study or are thinking of joining any other research study.



You should make your own decision about joining this study. However, we encourage you to discuss your decision with your partner and other people who are important to you. You can share this booklet with others. The study staff also have flyers about the study that they can give you.



You can invite your partner or other people to the clinic for information about this research study.

To properly test if the gel or tablets prevent HIV, it is important that women who join this research study come for all of their visits and use their gel or tablets every day that they are in the study. Study staff will give information and counseling to help women do this. Women are asked to speak freely and honestly with the study staff, so they can be given any help they may need.



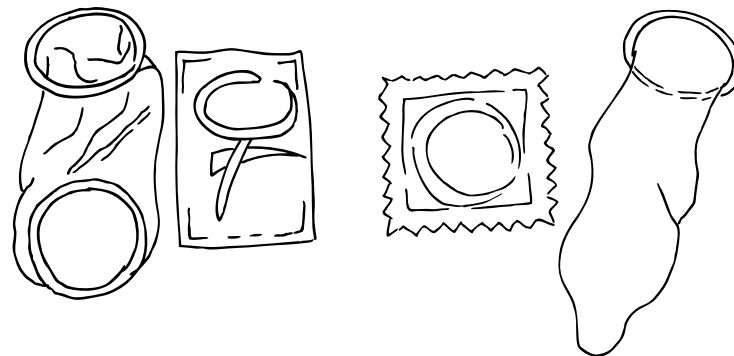
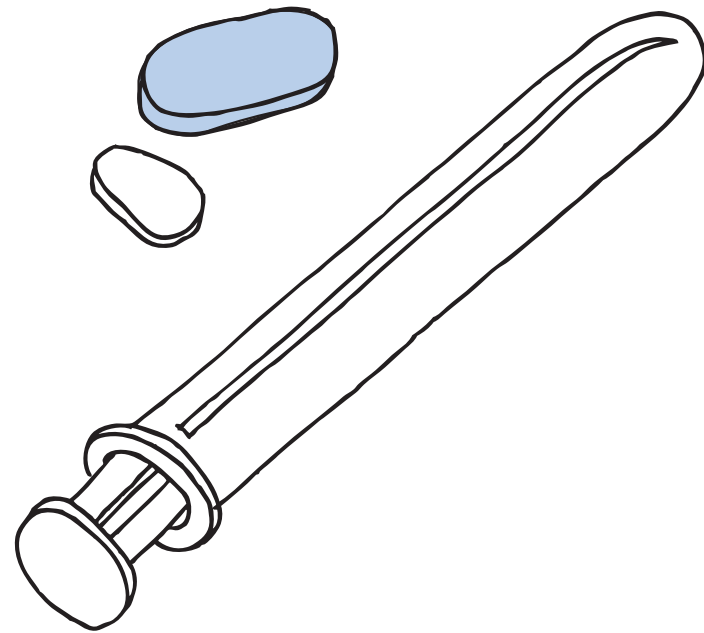
As you think about joining this study, remember that you will be asked to use gel or tablets every day and to have clinic visits every month for 1-3 years. Please think carefully about whether this will be possible for you. If you are not able to do this, you should not join this research study.

Women who join this research study may quit the study if they feel they must. If you decide to join, we hope you will try to stay in the study until it is finished, so we can learn if the gels or tablets prevent getting HIV.



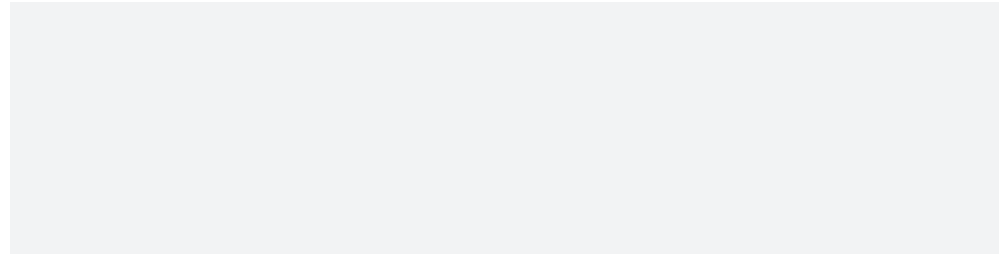
There are things we do not know about the gel and tablets. That is why we are doing this research study. As you think about joining the study, please know:

- Some women in the study will use Tenofovir gel, Tenofovir tablets, or Truvada tablets.
- Other women will use placebo gel or placebo tablets.
- No one can tell who is using which gel or tablets until the study is finished.
- It is not known if Tenofovir gel, Tenofovir tablets, or Truvada tablets prevent getting HIV.
- Condoms are the only known way to prevent getting HIV through sex. To be safe, use a condom correctly every time with every partner.

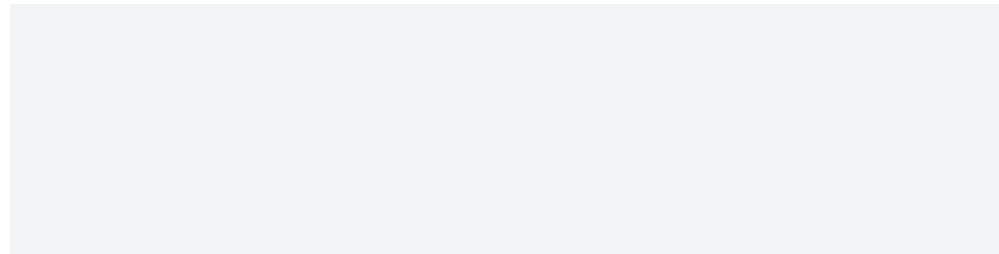


For Additional Information Or Questions

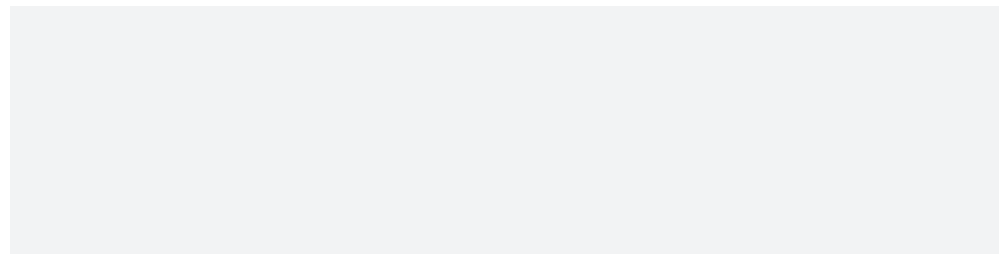
This research study is being conducted by:

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If you have questions about this research study, please contact:

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If you have questions about the rights of women who join this research study, please contact:

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The United States National Institutes of Health is paying for this research study.