

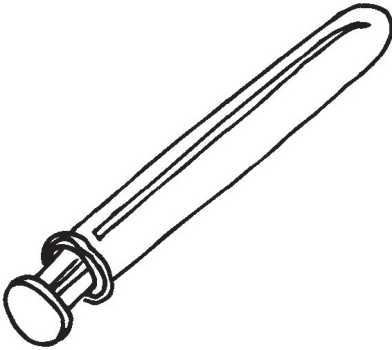
The MTN-017 Study



Something new may help males and transgender females who have sex with men reduce their risk of getting HIV/AIDS.

The staff would like to tell you about a study being done to see if a pill or rectal gel to prevent HIV would be safe for males and transgender females who have sex with men. The study will also help to see which they may like using better.

The study is called the **MTN-017 Study**. This study is testing two different products:



RECTAL GEL

The rectal gel contains a drug called tenofovir, which is an ARV. An antiretroviral (ARV) is a drug that is used to treat people with HIV/AIDS. This gel has been formulated for use in the rectum.



ORAL TABLET

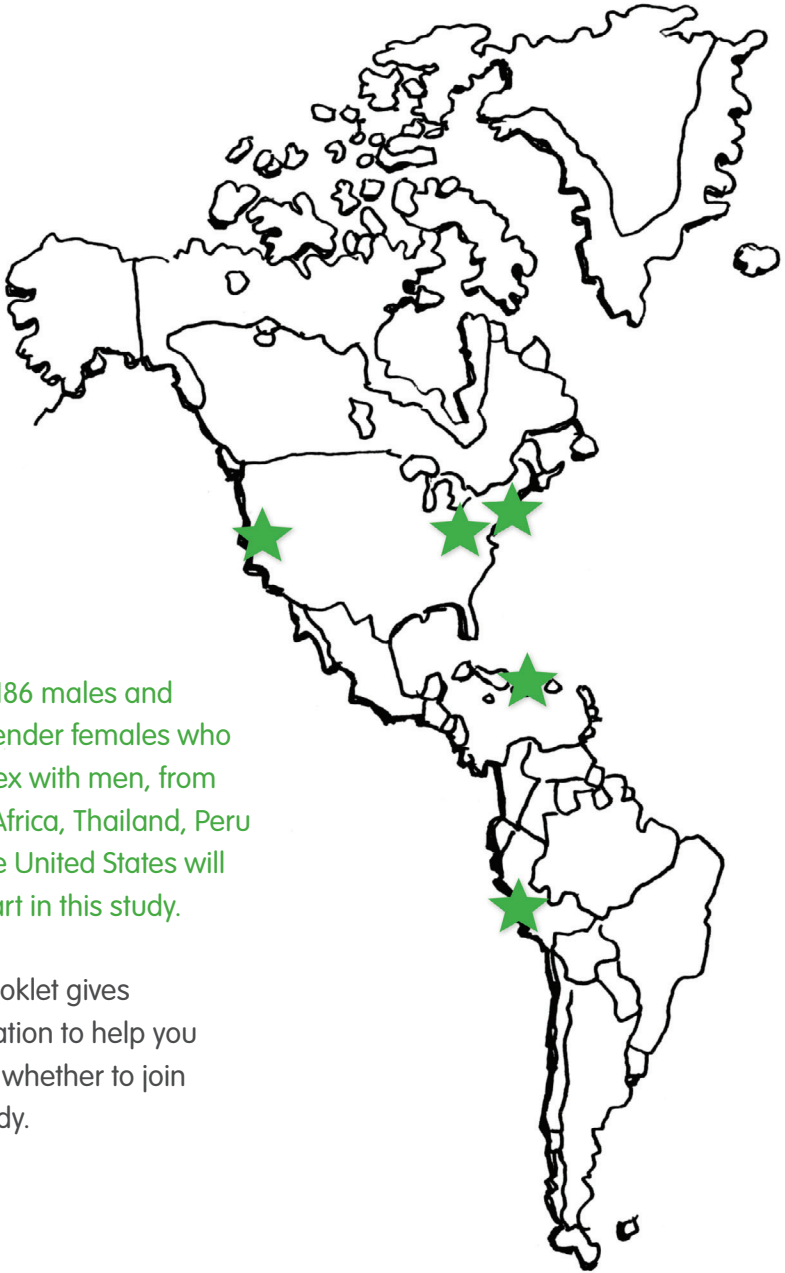
The tablet is called Truvada. Truvada is a combination ARV containing tenofovir and emtricitabine.

This research study will see if:

- A gel inserted into the rectum daily
- A gel inserted into the rectum before and after anal sex
- A tablet taken by mouth daily

are safe and if males and transgender females who have sex with men would use them.

ABOUT THE RESEARCH STUDY



About 186 males and transgender females who have sex with men, from South Africa, Thailand, Peru and the United States will take part in this study.

This booklet gives information to help you decide whether to join the study.

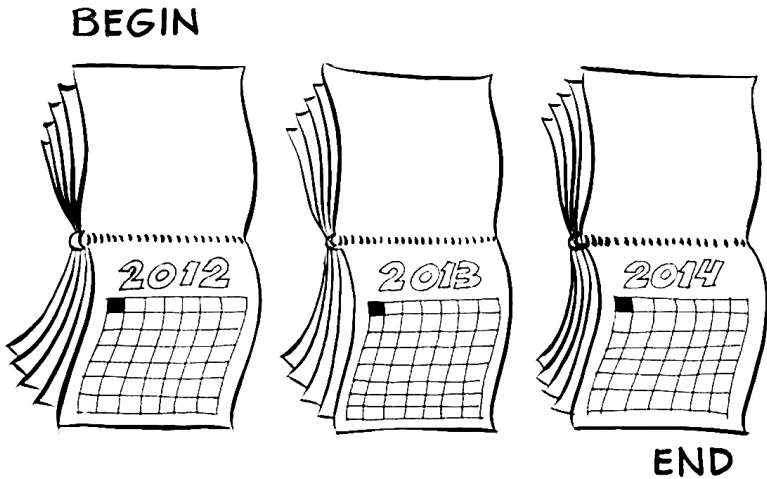


ABOUT THE RESEARCH STUDY

This study is testing three different possible HIV prevention regimens which are to:

- use the rectal gel daily or
- use the rectal gel before and after anal sex or
- use a tablet daily

A regimen is the way you are asked to take a certain product. The study will take about 2 years from the time the first person joins until the time researchers have the study results.



If you decide to join this study, you will be in the study for approximately 27 weeks (6–7 months), starting on the day you sign the informed consent form.

You will be assigned to 1 of 6 groups in this study, shown in the table below. Each group will follow a different order of using the study regimens. You will use each regimen for 8 weeks. Each 8 weeks of product use is called a period. There are 3 periods in this study. Between each period, there is about one week when you will not be taking a tablet or using the rectal gel. You will use all three study regimens.

Group	Period 1 8 weeks	No product ~1 week	Period 2 8 weeks	No product ~1 week	Period 3 8 weeks	Follow Up ~1 week
1	Tablet Daily		Gel Daily		Gel with anal sex	
2	Gel with anal sex		Tablet Daily		Gel Daily	
3	Gel daily		Gel with anal sex		Tablet Daily	
4	Gel daily		Tablet Daily		Gel with anal sex	
5	Tablet daily		Gel with anal sex		Gel daily	
6	Gel with anal sex		Gel daily		Tablet daily	

The order in which you will use the study regimens is chosen by chance, like throwing dice or flipping a coin. Neither you nor the study staff can choose or change the order you use the products.



STUDY VISITS



You will come to the clinic at the beginning, middle and end of each period.

During each period you will receive a phone call from study staff to see how you are doing:

- 2–3 days after you start the period and
- 2 weeks later



At each visit you will:



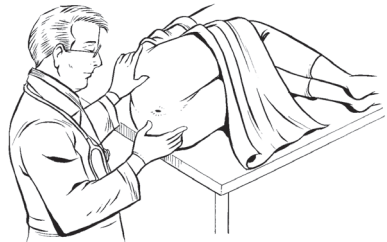
- Be given condoms and lubricant
- Be counseled on ways to reduce your risks of getting HIV



- Answer questions about your health and sexual behaviors
- Answer questions about your use of rectal gel or tablets



- At some visits, you will have an examination of your body. Some examinations will include the genital area and inside the rectum.



STUDY VISITS

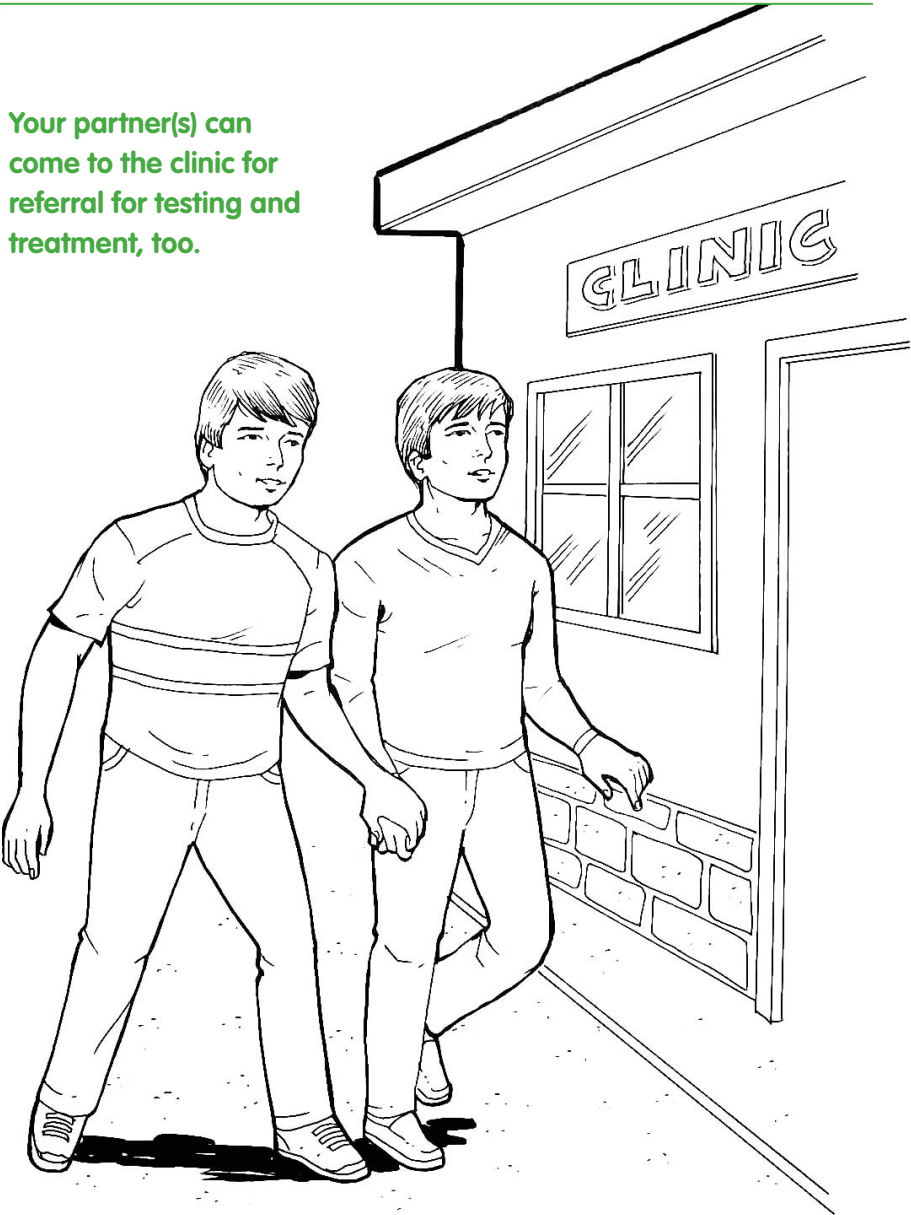


You will also have tests of your blood, urine and rectum to check your health and for sexually transmitted infections (STIs), including HIV.

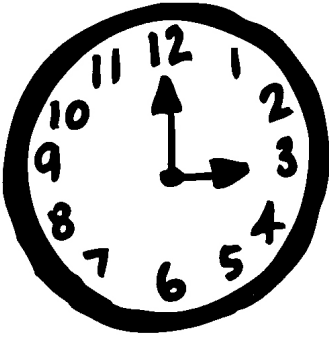
If you get an STI, other than HIV, you will be counseled and treated or referred for treatment.



Your partner(s) can come to the clinic for referral for testing and treatment, too.

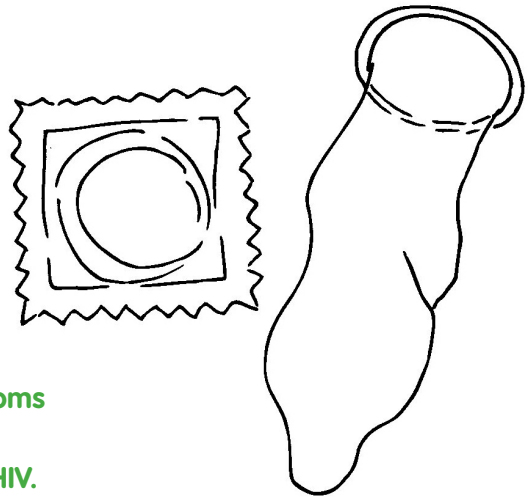


STUDY VISITS



Visits to the clinic may take several hours so you will need to plan for this. You will be reimbursed for coming to the clinic for study visits.

We do not know if the rectal gel will prevent you from getting HIV. One study has shown that the tablet is effective in preventing HIV in males and transgender females who have sex with men.



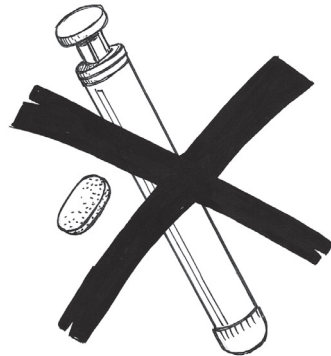
It is important to use condoms every time you have sex to reduce the risk of getting HIV.

Male Condom



The clinical staff will also talk to you about other HIV prevention methods. If you get HIV while in the study, you will stay in the research study if you choose to and be counseled and referred for the care and treatment you may need.

You will stop using the rectal gel or tablets. You may also stop using the rectal gel or tablets due to other health problems. Even if you stop using the rectal gel or tablets, you may stay in the research study.

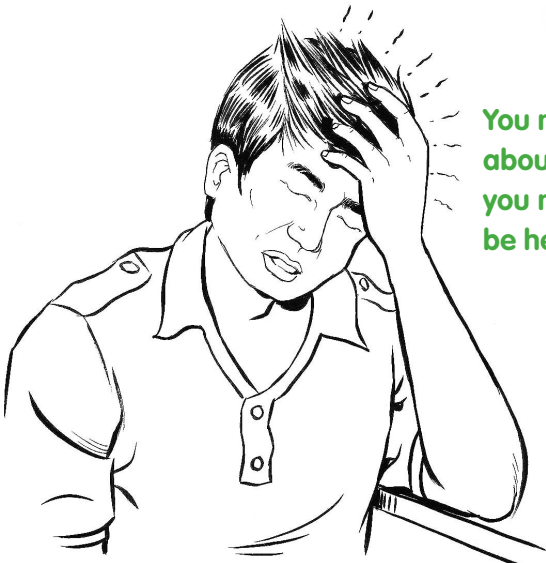


RISKS

You may not like answering personal questions or having blood tests or physical examinations. You may become embarrassed or worried. The study staff will talk to you about any concerns you have. The study staff will not tell anyone you are participating in the study and will make every effort to protect your privacy while you are taking part in the study.

The rectal gel and tablets could cause some side effects. They may include:

- Pain, itching, or discomfort in the rectum when using the gel
- Headaches, body pain, body weakness, rash, fever, nausea, diarrhea, or dizziness when using the tablets
- Problems with your kidneys, liver, and bones
- The rectal gel and tablets could cause other problems we do not know about



You must tell the study staff about any health problems you may have, so you can be helped.



It may be possible to get HIV while using the rectal gel or tablets. If you use the rectal gel or tablets after getting HIV, these products may not work for you as treatment for HIV/AIDS. For this reason, you will have HIV tests several times during the study, and must stop using the rectal gel or tablets if you get HIV.



You must never share or sell your rectal gel or tablets. If other people who have HIV use the rectal gel or tablets, these products may not work for them as a treatment for HIV/AIDS.

BENEFITS



There are no direct benefits from participating in this study, but others may benefit from the information learned from the study. You will have tests and examinations to learn about your health. You will get condoms and counseling on how to prevent STIs including HIV.



You will receive treatment or referrals for medical care, counseling, and other services available locally if you are found to be infected with STIs, other than HIV, and other illnesses.

Your partner(s) can be given counseling and referral for testing and treatment for STIs.



It is your choice whether to join this study. You may ask questions to help decide whether to join this study. Please continue to ask questions at any time, even after you join the study. If you decide not to join this study, it will not affect your health

care. You may join other studies in the future if you are eligible. If you join this study, the study staff must keep all information about you confidential. They will keep your information locked away where no one outside of the study can see it.



VOLUNTARY AND CONFIDENTIAL

If you join this study, you cannot take part in other research studies until you finish this study.



This is important for your safety. For researchers to be able to understand if the rectal gel and tablets are safe, we ask that you:

- Please tell the study staff if you are in another research study or are thinking of joining another research study
- Remember you cannot take part in any other study until you finish this study
- Come for all your study visits
- Use the products as instructed by study staff

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. Participants who join this research study may quit the study at any time. If you decide to join, we hope you stay in the study until it is finished, so we can learn if these products are safe and will be used by others.



We encourage you to discuss your decision with your partner(s) and other people who are important to you.



You are asked to speak freely and honestly, with study staff, so they can know how to help you. You may share this booklet with others.

As you think about joining this study, remember that you will:

- Be asked to use a tablet or rectal gel every day, or the rectal gel every time you have sex, as instructed, during your participation in this study
- Have clinic visits regularly for 6–7 months
- Have blood tests, physical and rectal exams, and answer personal questions during your participation in this study
- Stay in the study for approximately 27 weeks

FOR ADDITIONAL INFORMATION OR QUESTIONS

This research study is being conducted by:

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

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

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