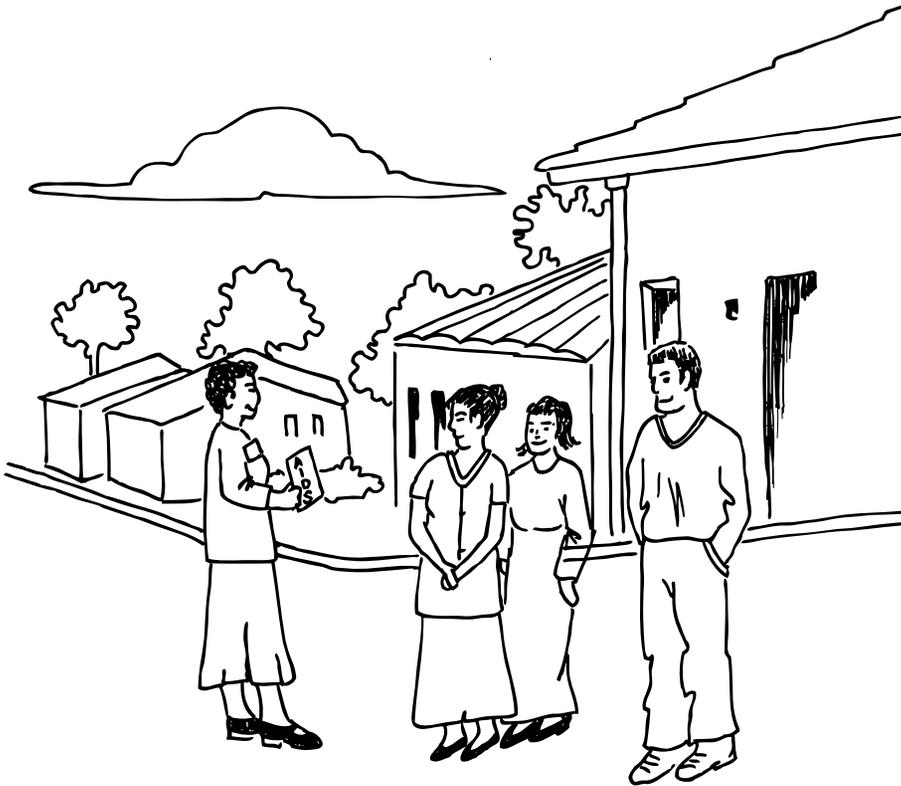


The **ASPIRE** Study



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

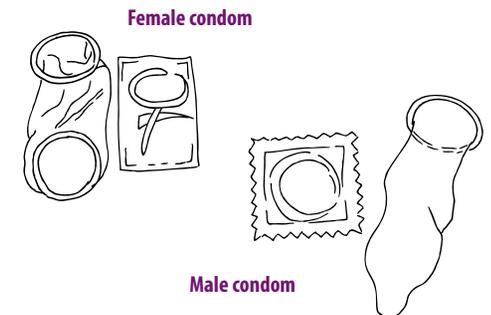


1. Not having sex

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



3. Using a condom correctly every time you have sex



Something New May Help Prevent Getting HIV



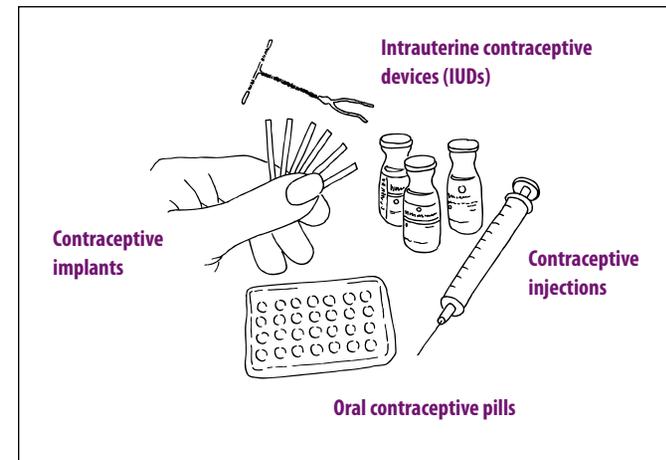
Studies are being done to test if vaginal rings that contain certain medication may prevent getting HIV.

As of today, no vaginal rings that contain these medications have been shown to prevent getting HIV, but researchers are trying to find products that will work.

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 are safe and prevent getting HIV.



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

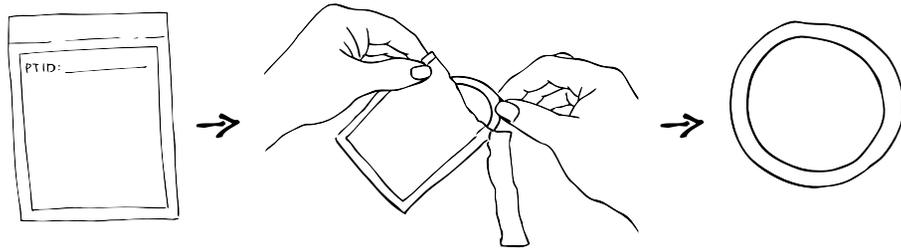


The staff here would like to tell you about a research study being done to try to find ways to prevent women from getting HIV. This research study is called ASPIRE (A Study to Prevent Infection with a Ring for Extended Use).



About The Research Study

The researchers here are doing this research study to test a vaginal ring that contains a study medication called dapivirine.



The ring is therefore called a dapivirine ring.

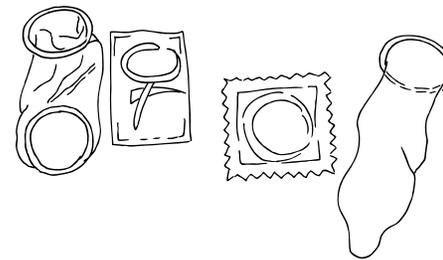
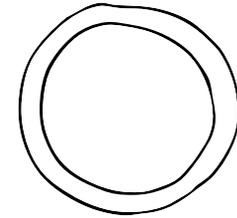
This research study will test if this study medication, contained in the ring, prevents women from getting HIV.



Thousands of women from multiple countries in Africa will take part in this research study.

You may be eligible to join this research study. This booklet gives information to help you decide whether to join the study.

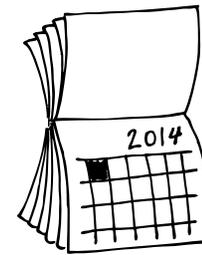
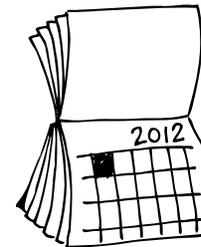
This research study is testing whether a vaginal ring containing dapivirine can help to prevent the transmission of HIV from a man to a woman during sex.



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

The study will take about 3 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 1-2 years, depending on when she joins.**

BEGIN

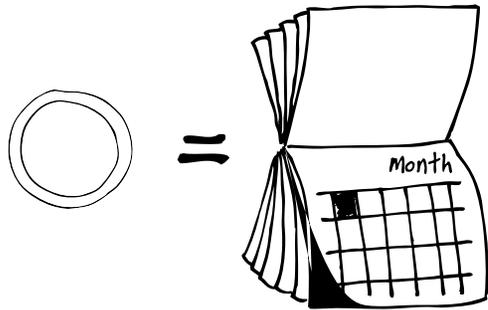


END



While in the research study, all women will be asked to place a ring in her vagina and not remove it for a month. A clinician can help her insert the ring if she wants.

After one month, the woman or the study clinician will remove the ring and replace it with a new ring.



Women should **not** remove the ring for sex, bathing, or during menses.



Women in the research study will be tested for pregnancy, HIV, and other sexually transmitted infections (STIs). The pregnancy tests are needed because the dapivirine ring has not been tested in pregnant or breastfeeding women.

The dapivirine vaginal ring in this study does not contain contraception and will not protect against becoming pregnant.

Women who are pregnant, breastfeeding, or who 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.



Study Groups

There are 2 groups of women in the research study.



Dapivirine ring



Condoms

One of these groups is given a dapivirine ring.



Placebo ring



Condoms

The other group is given a placebo ring.

The placebo ring looks and feels like the dapivirine ring, but does not contain dapivirine or any other active medication.

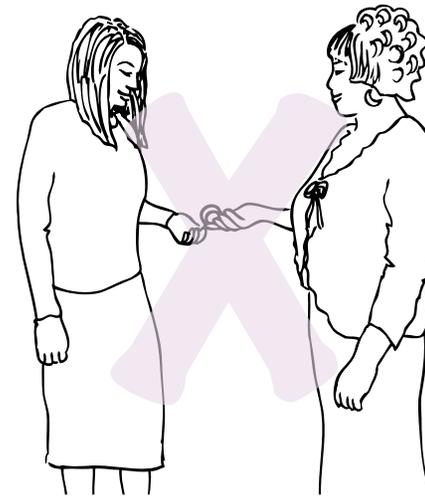
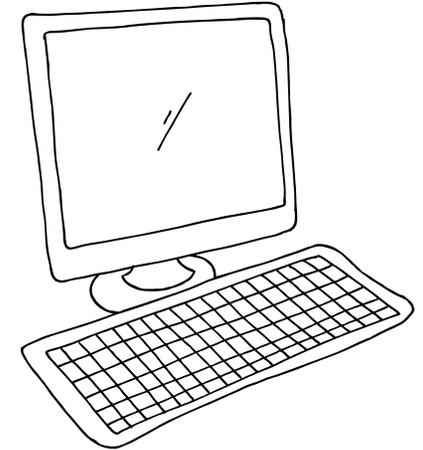
You may wonder why some women are given dapivirine ring while others are given placebo ring. The placebo ring is needed for researchers to understand the effects of dapivirine. No one will know which women are using the dapivirine ring, and which are using placebo ring, until the study is finished. The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

All women have an equal chance of being placed into 1 of the 2 groups.

Each woman's group 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.

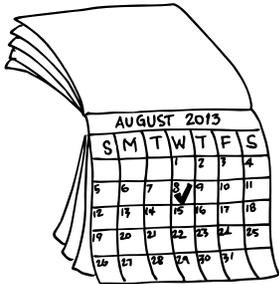
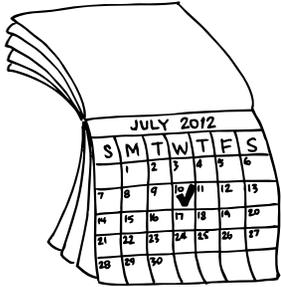
Once a woman is placed in a group, she must accept that group. She cannot change her group.



No sharing

To properly test if the dapivirine ring prevents getting HIV, it is very important that women in the study use the ring they are given as they are instructed. For this reason, women must never share or sell their ring.

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 the ring
- Discuss ways to prevent pregnancy and receive family planning if needed
- Discuss ways to prevent getting HIV



- Have a urine test for pregnancy
- Have a blood test for HIV
- Be given condoms
- Provide vaginal swab samples
- Remove their vaginal ring and insert a new vaginal ring or have the doctor or nurse do this



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.

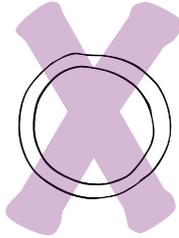


If women get an STI, they will be counseled and treated.

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 who are pregnant or want to fall pregnant in the next 2 years will not be eligible to join the study. But if they do fall pregnant after joining the study, they will stay in the study and will be referred for antenatal care. They may also be referred to other studies. They will stop using the ring 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 the ring.

Women may also stop using the ring due to other health problems.

Even if a woman stops using the ring, she will stay in the research study. They may also be referred to other studies.

Risks



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.

The dapivirine ring and the placebo ring could cause problems. Women who use either ring may have pain, itching, or discomfort in the genital area.



The rings could cause other problems we do not know about. Study staff will discuss other possible side effects.

Women must tell the study staff about any health problems, so they can be helped.

Some women may get HIV while in the study. For this reason, women are tested for HIV at every visit, and must stop using the ring if they get HIV.



Benefits

Women may feel some satisfaction from helping to find ways to prevent getting HIV.

We hope the dapivirine ring can help, but we cannot know if it works 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.

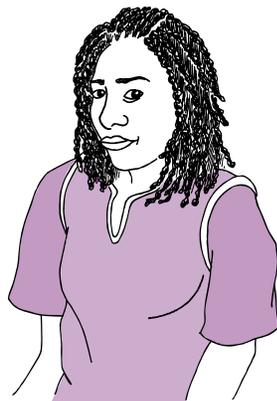
They will receive treatment for STIs and referrals for treatment of other illnesses.



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.



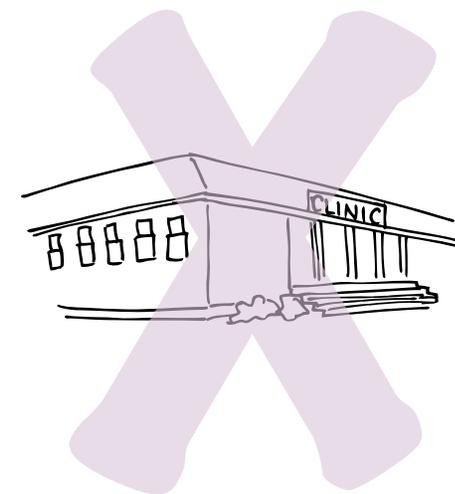
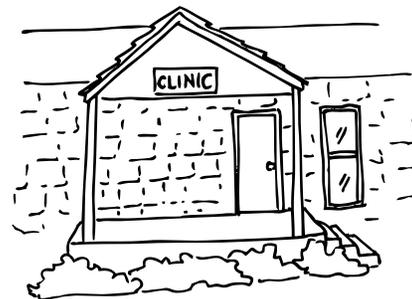
If you join this research study, the study staff must keep all information about you confidential.

They will keep your information locked away where no one else can see it.

If you have participated in other HIV research studies recently, you may not be eligible to join ASPIRE.

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 ring being tested in this study is safe and works 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.



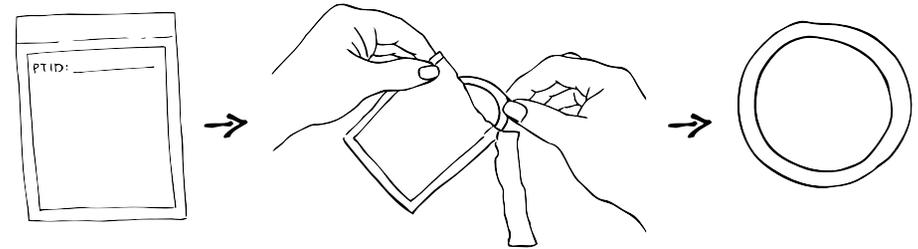
You can share this booklet with others.
You can invite your partner or other people to the clinic for information about this research study.

To properly test if the ring prevents HIV, it is important that women who join this research study come for all of their visits and use their ring as instructed.

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.

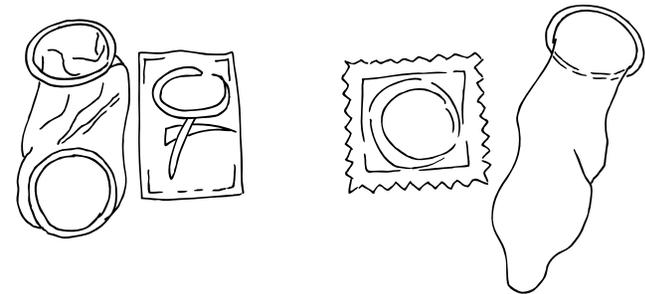


There are things we do not know about the ring. That is why we are doing this research study.



As you think about joining the study, please know:

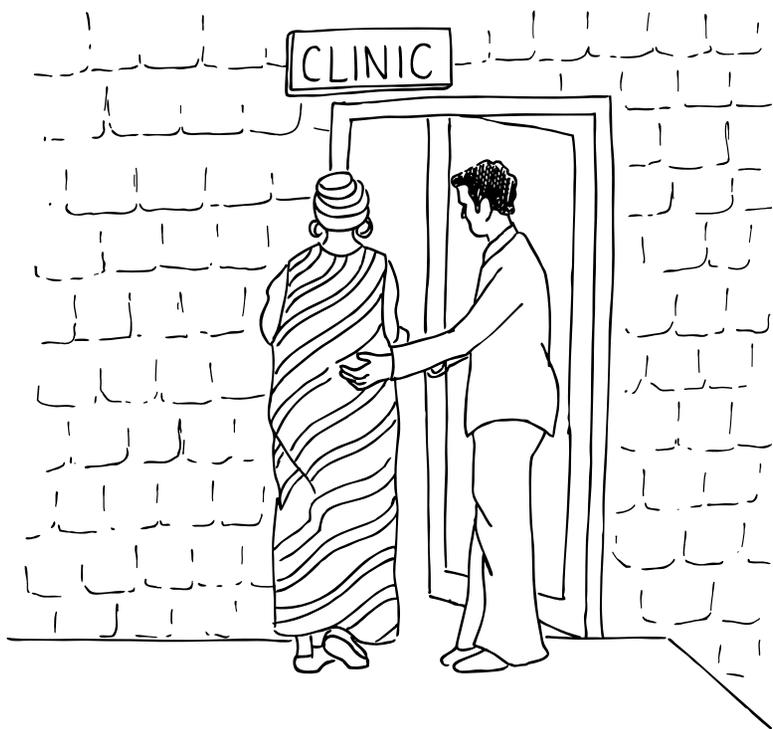
- Some women in the study will use dapivirine ring.
- Other women will use placebo ring.
- No one can tell who is using which ring until the study is finished.
- It is not known if dapivirine ring prevents getting HIV.
- Condoms are the only known way to prevent getting HIV through sex. To be safe, use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



As you think about joining this study, remember that you will be asked to keep the ring inserted, and to have clinic visits every month for the next 1-2 years.

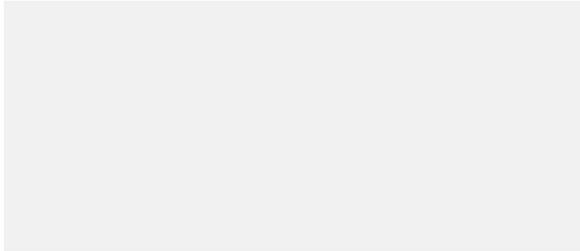
Please think carefully about whether this will be possible for you. If you are not able to do this, you should not join this research study.

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 ring prevents women getting HIV.

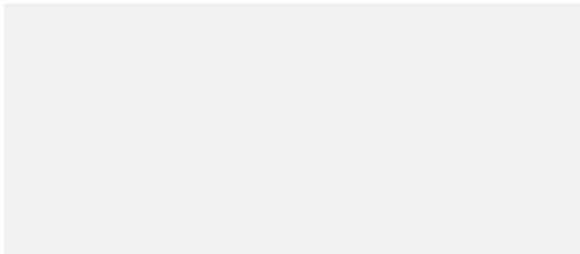


For Additional Information Or Questions

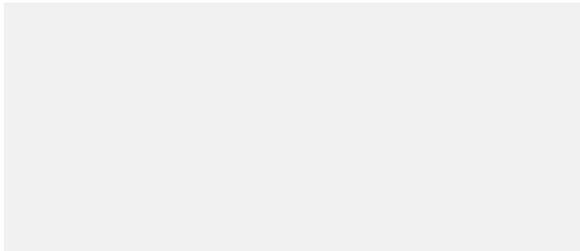
This research study is being conducted by:



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



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



The United States National Institutes of Health is paying for this research study.
The International Partnership for Microbicides is providing the rings for this research study.