

This letter gives information about a research study for women called ASPIRE.



Why is this study being done?

Since there is no cure for HIV/AIDS, studies are being done to find ways to prevent getting HIV/AIDS. While some prevention methods such as condoms are available, more options are needed for women.

What is this study testing?

The ASPIRE study will test if a ring inserted in the vagina may prevent women from getting HIV. In order to test this, some women will receive rings containing study medication called Dapivirine. When the ring is in the vagina, the study medication is slowly released. Other women will be given rings that look exactly the same, but have no study medication. The study medication may help prevent HIV infection, but we do not know if it does.



Why are there two types of rings?

The two types of rings are needed in order to find out if the study medication is effective for preventing HIV. All women have an equal chance of being placed into 1 of the 2 groups. Women cannot choose their group. No one will know who has which type of ring until the study ends. At the end of the study, researchers will compare the two groups to see if the ring with study medication was effective for preventing HIV.

What will women in ASPIRE be asked to do?

Women will be asked to:

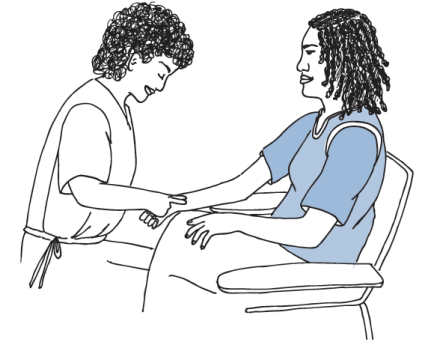
- Wear a vaginal ring every day for about 1-2 years
- Visit the clinic every month to get a new ring
- Answer questions about their health and their ring use
- At some visits, have health examinations
- Have laboratory tests to check on their health, including tests for pregnancy and HIV
- Receive counseling and condoms

Who can join this study?

Thousands of women from up to 5 African countries will take part in ASPIRE. Some women who wish to join may be eligible, and some may not. Women must be in good health, HIV negative, and not pregnant. Women must visit the clinic to find out if they can join.

What are the risks?

It is possible that some women will feel uncomfortable wearing the ring. Some women may have itching or other symptoms. Some women may be embarrassed by questions and procedures in the study. The research staff will be available to help women if they have these problems.



What are the benefits?

Women in the study will receive medical exams, tests to check on their health, and HIV counselling and testing. Women who decide to join the research study are helping to find ways to prevent HIV/AIDS.



What can partners and community members do?

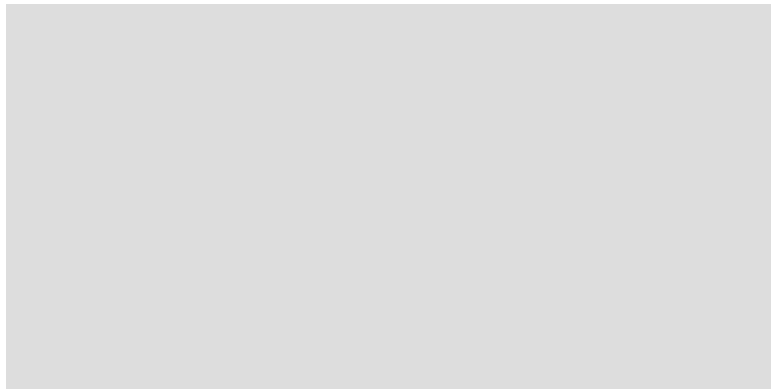
For women who are eligible, deciding whether to join ASPIRE is an individual choice. Women are encouraged to discuss their decision with their partners and other people who are important to them. Study staff will keep information about women in the study confidential. However, study staff are available to talk about ASPIRE and answer any questions partners or community members have. By being supportive, partners and community members are also helping to fight HIV/AIDS.

Remember, it is not known if the medication in the vaginal ring will prevent getting HIV. To prevent getting HIV, women in the study are counseled to use condoms every time they have sex.

If you have questions or need more information, please visit the study clinic:



If you have any immediate questions or concerns, you may also contact:



ASPIRE

A Study to Prevent Infection
with a Ring for Extended Use

Information for women, their
partners and the community

