

REVERSING THE EPIDEMIC IN AFRICA
WITH CHOICES IN HIV PREVENTION
REACH
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This study is being done to see if a vaginal ring or oral tablet is safe in young women and to better understand how young women use these products.

Who can join this study?

Three hundred young women, ages 16 to 21, from four (4) African countries will take part in REACH. Young women must be in good health, HIV negative, and not pregnant. Women must visit the clinic to find out if they can join. If using a tablet or a vaginal ring every day is not something you think you can do, then this study may not be right for you.



How do the products work?

Both products contain drugs that have been shown to prevent HIV. The vaginal ring has a medicine called dapivirine inside. It was used before by women 18 years and older and it safely prevented women from getting HIV when used regularly.

Young women (under the age of 22) also used the ring but were not protected from getting HIV because they did not use the rings consistently. For this reason, we are trying to learn if young women would be willing to use the ring, and to make sure it is safe for them to use.



The tablet, contains two medications called emtricitabine and tenofovir disoproxil fumarate. The tablet has been proven to prevent HIV in adult men and women. This same medicine is used to treat people that are infected with HIV.

Both products must be used regularly, to achieve the most protection from getting HIV.

How long will each young woman take part in the study?

If she agrees, she will be in the study for about a year and a half. She will use a ring for about 6 months, getting a new ring to use every month. She will also be asked to take a tablet once a day for 6 months.

The order that she takes the products (vaginal ring or tablet first) will be decided by chance, like flipping a coin. She will not be able to choose the order for herself. After the ring is used for 6 months and the tablets are taken daily for 6 months, she will then choose what she wants to use for the final 6 months of the study, or she can choose not to use either product.



What will she be asked to do if she decides to join the study?

Young women will be asked to:

- Provide consent to join the study; if she is under 18, her parent will be asked to give permission too
- Use a birth control method such as birth controls pill and other hormonal methods
- Wear a vaginal ring every day for about 6 months
- Take a pill by mouth every day for about 6 months
- Decide between taking the tablet or using the ring for 6 months or choose not to use either during the last 6 months of her participation in the study
- Visit the clinic every month to get a new ring or more tablets
- Answer questions about their health and their use of the ring and tablets
- At some visits, have health examinations and laboratory tests to check on their health, including tests for pregnancy and HIV
- Receive counseling and condoms

What are the risks and benefits?

It is possible that some will feel uncomfortable wearing the ring. Some may have itching or other symptoms. Some who use the tablets may have an upset stomach and other symptoms but these side effects only last about a month and get better with time or go away completely. The people doing the study will offer any help if these problems occur.

Both the tablet and the vaginal ring may prevent young women from getting HIV if used regularly. She will get health exams, counseling and condoms. Each young girl will also be offered a vaccine that protects them from two diseases, hepatitis B and HPV. These vaccines can prevent cancer of the liver and the cervix.



All information that is collected in this study will be kept private and will not be shared with parents or anyone else.



For more information about REACH, go to: <http://www.mtnstopshiv.org/news/studies/mtn034>