



What were the results of the ASPIRE study?

Overall, the ASPIRE study (MTN-020) showed that the dapivirine vaginal ring prevented approximately one third of HIV infections. Among women older than 21, who used the ring more consistently than younger women, more than half of HIV infections were prevented. In ASPIRE, even greater protection was seen with higher adherence (more than two thirds). Like other prevention methods, the ring only works if used correctly and consistently. The ring was also safe,

meaning that it did not cause significant health problems. Another study that tested the dapivirine vaginal ring, called IPM-027 (The Ring Study), showed similar results. **This is a tremendous success that would not have been possible without the commitment of our study participants!**

When will the dapivirine vaginal ring be available in our communities?

IPM, the group that developed the ring, is working with governments and other partners with the goal of making the ring available in our communities. This process involves many regulatory and country-specific approvals and each one takes time. We do not know if the ring will be approved, or exactly how long before the ring may be available, but the process often takes several years.

Why is the HOPE study being done?

HOPE is an Open-Label Extension (OLE) study, designed to offer participants access to an effective study product before it is available in the community. Open-Label Extension studies are also conducted to collect additional information about the product, like about safety and adherence. **The primary purpose of the HOPE study is to offer participants immediate access to the dapivirine vaginal ring, which has been shown to be safe and to decrease the risk of getting HIV.**

Who is eligible for the HOPE study?

Currently, only women who participated in the ASPIRE study will be considered for enrollment into HOPE. Women must understand the study requirements, and agree to take part. Women must be in good health, HIV negative, and not be pregnant or breastfeeding. Women will have medical tests and exams to confirm that they are eligible for HOPE.

How long is the study? How often are study visits?

Each woman who enrolls will be in HOPE for about 1 year. Study visits will be monthly for the first three months, and then once every three months after that.

What are the vaginal rings like in HOPE?

All women will be offered a vaginal ring containing dapivirine for monthly use. Unlike ASPIRE, there are NO placebo rings (without medication) in HOPE.

What will women who enroll in HOPE be asked to do?

- All eligible participants will be invited to join HOPE and attend regularly scheduled study visits.
- All participants will be offered the dapivirine vaginal ring to use monthly. Women can join the study regardless of whether they choose the ring as an HIV prevention method or not.
 - Women who choose the ring as an HIV prevention method will receive counseling and instructions about ring use and will be asked to answer questions about ring use.
 - Participants can change their mind about using a ring even after joining the study. All participants make important contributions to the study as long as they **tell study staff when they are not using the ring**. Remember, though, that the ring can only protect against HIV when it is used.
- All participants, regardless of ring use, will be asked to:
 - Answer questions about their health and sexual behaviors
 - Receive risk reduction counseling and condoms
 - Use a family planning method to prevent pregnancy
 - At some visits, have health examinations
 - Have laboratory tests, including tests for STIs, pregnancy, and HIV
 - Provide blood, hair, and vaginal swab samples

What about women who decline enrolment into HOPE?

- If a participant decides she does not want to enroll in HOPE, she will be asked if she is willing to have one visit to provide information about why she is declining enrollment.
- Participants who decline enrollment may change their mind and enroll in HOPE, provided that the study is still ongoing and they meet eligibility requirements.

What are the risks?

The risks of participating in HOPE are similar to ASPIRE:

- You may feel discomfort or pain from the exams or blood draws.
- The vaginal ring may feel uncomfortable to some women, and some may have itching, discharge, or other symptoms.
- You may be embarrassed by questions and procedures in the study.
- It is possible that you or your partner may feel the ring during sexual activity.
- In the unlikely event you become infected with HIV, you may develop drug resistance if you continue to use the ring.
- It is possible that others may treat you unfairly or discriminate against you for participating in the study.

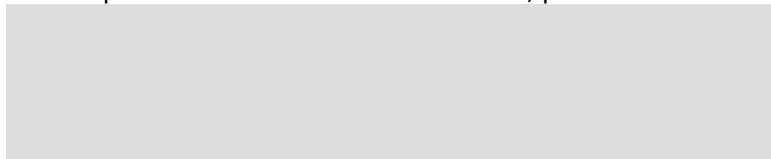
What are the benefits?

- During study participation, women in HOPE will be offered access to a vaginal ring that has been found to be safe and effective for HIV prevention.
- Women in the study will also receive medical exams, tests to check on their health, family planning, HIV/STI counselling and testing, and treatment or referrals, as needed.

What can partners and community members do?

For women who are eligible, deciding whether to join HOPE and whether to use the ring 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, but are also available to talk about HOPE and answer any questions partners or community members have, as needed. By being supportive, partners and community members are also helping to fight HIV/AIDS.

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



HOPE

Out of ASPIRE, there is HOPE

Information for women, their partners and the community

