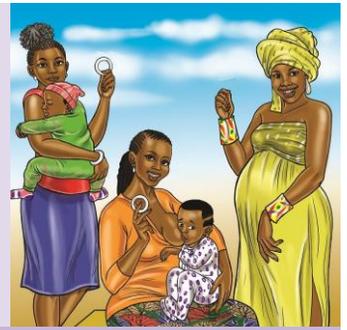




Study Overview



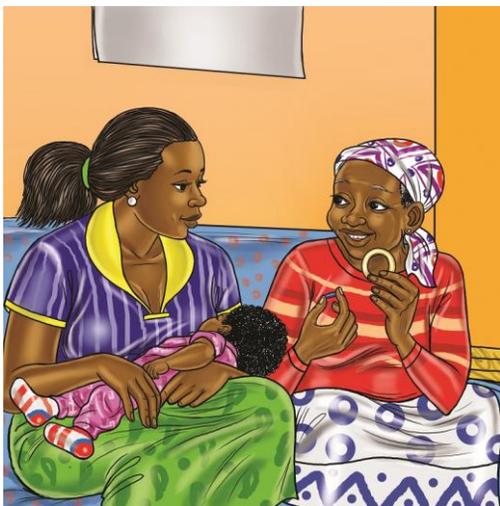
The B-PROTECTED study intends to learn whether two safe and effective HIV prevention methods, the dapivirine vaginal ring and oral Truvada are also safe to use during breastfeeding

Who will join the B-PROTECTED study?

About 200 pairs of breastfeeding women and their breastfed babies from Malawi, South Africa, Uganda, and Zimbabwe will take part in the study.

What is the study design?

- Mothers and their babies will enroll together in the study. The mother will use either the dapivirine vaginal ring or oral Truvada for three months while breastfeeding.
- Women will have about 8 study visits over a period of three and a half months. Study visits are more frequent during the first month of study participation and occur approximately once a month after that.



Who can participate?

- Women who do not have HIV and are 18-40 years old with a healthy, exclusively breastfed baby between 6-12 weeks old may be eligible to participate if other eligibility criteria are met.
- Women must be **willing to be assigned by chance** to use either daily oral Truvada or the monthly dapivirine vaginal ring while breastfeeding their baby.
- Women must be using an effective contraceptive method, planning to continue exclusive breastfeeding for the duration of the study, and willing to attend study visits with their baby.

How are study products assigned?

Participants will be randomized (assigned by chance) to use either the dapivirine ring or oral Truvada pills. Neither participants nor study staff can decide which product participants receive.

How long are study visits?

Study visit length depends on the type of visit. Most visits will last a few hours, but some may be shorter or longer. Study staff will try to work with participants' schedules.

What will women do at their study visits?

- Receive either one new ring or a month's supply of pills each month in the study.
- Have health exams, answer questions about their health, provide vaginal fluid, blood, urine, and breast milk samples for testing and allow study staff access to medical records.
- Receive HIV testing and counseling about how to protect themselves from HIV and other STIs.
- Women may answer questions about the use of their assigned study product and their sexual behaviors. Some women will be asked to complete one longer interview during study participation.
- Bring their baby to the clinic for health exams, blood draws, and laboratory tests to check their health, including testing for HIV if needed.
- Answer questions about their baby's health.

How will participant samples be used?

Blood, pelvic, breast milk and urine samples taken at study visits will be tested to monitor the participant's health and answer the study research questions. Participants will receive test results when they are available. Samples are stored in special laboratories and only study staff have permission to access them.

Does being in the study cost anything?

No, there is no cost to participate in the study. The study staff will reimburse participants for their time and effort, and cost of trips to come to the clinic.

What are the risks of joining the study?

- Women or their babies might experience side effects from the drugs in the study products.
- Participants may feel discomfort from having blood tests or physical exams done.
- Women might feel uncomfortable answering questions about their personal life.
- Women might feel worried about getting test results for themselves or their babies.
- Others may find out about being in the study and may treat women or their babies poorly or unfairly.

How will risks be addressed?

Most procedures done in this study are routine medical procedures and pose little risk to women and their babies. The study staff will help with any health problems or side effects that happen during the study, and provide counseling. Staff will keep all participant information private.

What are the benefits of joining the study?

- Women and their babies will have access to medical exams, tests, clinical care, and care referrals. Study staff will provide women counseling, and offer condoms.
- Women will have access to the dapivirine ring or oral Truvada as an HIV prevention method. If used consistently, these products can help reduce a woman's and her baby's risk of HIV.
- Information learned from this study may help expand available HIV prevention options for breastfeeding women.

What if participants get HIV during the study?

Being in this study will not cause HIV infection for women or their babies. However, it is possible for anyone to get HIV or other STIs from sex or other risky activities.

If women or their babies test positive for HIV during the study, study staff will help them get treatment and other services for HIV. Women will stop using their assigned study product, but they and their babies can still come for study visits.

Protecting choices

Women are free to make their own choice about joining the study and may withdraw participation at any time.

Participants are encouraged to ask questions and involve their partner(s) or other individuals who are important to them in their decision-making. **Staff can provide study information to share with loved ones, or invite them to the clinic to learn more about the study.**



For more information about B-PROTECTED go to:

<http://www.mtnstopshiv.org/news/studies/mtn043>

Contact study staff **<site name contact information>**