What are the risks and benefits of participation?

Participants may feel anxious or embarrassed when discussing their health and sexual practices, study test results, and ways to prevent HIV/STIs. Use of the study products may cause temporary side effects such as gas, bloating, or diarrhea. Giving blood, rectal, throat and vaginal samples and having physical exams may cause mild discomfort. Participants could also experience discrimination or be treated unfairly if others learn about their involvement in the study. Staff will do all they can to minimize these risks.

Participants may not receive any direct benefit from participation in this study but will be contributing to vital HIV prevention research that may assist others in the future. In addition, participants may learn more about HIV and other diseases, have health exams, receive HIV and STI risk-reduction counseling and get referrals for other care if needed. Free male condoms will also be available to all participants.

Other Points to Consider

- Taking part in this study is completely voluntary. Participants may stop taking part at any time.
- All information collected about participants is kept confidential.
- All study products, examinations, and related care will be provided at no cost to participants.
- Participants will be paid for their time and effort.
- Taking part in this study does not take the place of medical care provided by participants' personal health care providers.
- The study staff will fully explain the study details to participants and are available to address any questions participants may have.

MTN
microbicide trials network

MTN-035: Information Booklet

For more information, go to:
https://mtnstopshiv.org/research/studies/mtn-035

[Sites to insert contact information]

What is the purpose of this study?

This study will assess the safety, tolerability and acceptability of, and adherence to, three potential methods of delivering anti-HIV drugs into the rectum prior to receptive anal sex. The information collected during this study could lead to new options for preventing HIV among those who engage in receptive anal sex.

Who can join this study?

Men who have sex with men (MSM), transgender men, and transgender women ages 18-35 who are HIV-negative, in good general health and have a history of engaging in consensual receptive anal sex at least three times in the past three months, with the expectation to maintain this frequency during study participation, may be eligible to join this study. This study will enroll about 210 participants from seven research sites in the United States, South Africa, Thailand, Peru, and Malawi.

What products will be used in the study?

Participants will be asked to use three rectally-administered products prior to engaging in receptive anal sex for four weeks (one month) each:

Rectal Douche – also called an enema, uses water to rinse the rectum with the intent to clean it.

Rectal Suppository – a small solid dosage form that dissolves or melts when inserted into the rectum.

Rectal Insert – a small solid dosage form that dissolves or melts when inserted into the rectum.

The products used in this study are placebos, meaning they do not contain any active drugs. They do not provide protection against HIV or other sexually transmitted infections (STIs). Participants should continue to use HIV and STI prevention methods, such as condoms and pre-exposure prophylaxis (PrEP), while in the study.

The order in which participants use the three study products (douche, suppository, insert) will be decided by chance, like flipping a coin. Participants will not be able to choose the order themselves.

How long will each participant be in the study?

Each participant will be asked to complete a total of eight study visits, once every four and five weeks. The total length of study participation will be approximately 3 ½ months.

What will participants be asked to do in the study?

Participants will be asked to:

- Provide consent to join the study
- Attend all study visits and comply with study participation requirements
- Answer health-related questions and provide feedback on the three study products, in-person, by computer and via text message/SMS
- Refrain from using non-study rectally-administered products for the duration of study participation (*personal lubricants and enemas that do not contain N-9 are permitted*)
- Have physical, rectal and, if applicable, genital, or pelvic exams
- Provide blood, rectal fluid, urine, throat cultures, and, if applicable, vaginal fluid for testing
- Use effective birth control (for individuals who can get pregnant)
- Receive counseling about study adherence and HIV/STI risk reduction strategies