

Who is doing this study?

The study is being done by the BOTUSA Project, a collaboration between the Botswana government and the U.S. Centers for Disease Control and Prevention.

The Health Research Development Committee in the Ministry of Health and an ethics committee at the U.S. Centers for Disease Control and Prevention will review and approve the study procedures before we start and will check during the study to see that participants are safe. An international committee of scientists who are not part of this study will also look at the information we collect to see that participants are safe.

In addition, advice is given to the study team by a national reference group, community advisory groups in Francistown and Gaborone, and participant advisory groups in the two cities.

FOR MORE INFORMATION ABOUT THE TDF2 HIV PREVENTION STUDY

PLEASE CONTACT:

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Basic Facts About: The Botswana TDF2 HIV Prevention Study



Why do this study with young adults in Botswana?

In Botswana, many young women and men are getting infected with HIV, the virus that causes AIDS. There are several ways to protect against getting or giving HIV including: people who have tested negative being faithful to each other, using condoms correctly every time a person has sex, and choosing not to have sex for a while. But for many young adults, it is hard to behave safely all the time. And every time they behave unsafely, they take a chance on getting or giving HIV. In Botswana, sexually-active men and women younger than 30 are getting infected more rapidly than people at other ages so it is especially urgent to find additional ways to prevent HIV infection among them. Having more effective prevention tools will help to achieve the Vision 2016 goal of no new infections in Botswana youth.

What is Pre-Exposure Prophylaxis?

Pre-exposure prophylaxis is a medical term for giving antibiotics or vaccines before people come in contact with an infectious agent to try and keep them from getting infected when the contact occurs. We think this might also work for HIV prevention because:

- giving newborns an antiretroviral when they are born seems to help protect them from virus they are exposed to during birth

- giving a single antiretroviral to health care workers hours to days after they are exposed to HIV by a prick from a contaminated needle will protect most against getting infected
- giving antiretrovirals to monkeys before exposing them to SIV (the monkey form of HIV) protects most against getting infected

What are Tenofovir (TDF) and Emtricitabine (FTC)?

TDF and FTC are antiretroviral medicines that come together in a single pill. It is used, in combination with other antiretrovirals, to treat people who have HIV infection. It prevents HIV from growing and spreading in the body.

Why do we think it is safe?

TDF/FTC is widely used for treatment in the United States, Europe, and in some African countries but not yet in Botswana. For treatment of HIV infection, it is taken once a day, doesn't cause many side effects, and is very slow to develop resistance. It has been tested in a few people without HIV infection for a short period of time and it appeared to be safe for them.

How will the study be done?

We will invite 1200 men and women in Francistown and Gaborone to join the study. They must be citizens of Botswana, 18- 29 years old, already sexually active, and healthy. The study will be carefully explained and those people who fully understand the study will be asked to give

their consent to be in the study. We will help everyone in the study to reduce their risk of getting HIV infection by providing frequent counseling, diagnosis and treatment for sexually transmitted infections, and free male and female condoms. In addition, everyone will be given pills to take daily. Half of the people will be randomly assigned to take TDF/FTC and half will be randomly assigned to take a pill that looks and tastes just like TDF/FTC but has no medicine in it (a placebo). Study participants and staff will not know who is taking which pill. That way the hopes and fears we have about TDF/FTC will not affect what we see during the study.

We will see study participants once a month for at least 12 months so that we can see how they feel, how well they are doing in taking a pill every day, and how their sexual behavior may be changing. At each visit, we will do an HIV test and a pregnancy test for women. At some visits we will also do physical examinations and blood tests to check how TDF/FTC and placebo pills may be affecting people in the study. We will stop the pills if a study participant becomes infected or pregnant or there is evidence of developing health problems on the blood tests or exams.

Since often we cannot get people to use condoms every time they have sex, we expect that some people in the study will put themselves at risk from time- to-time and become exposed to HIV. At the end of the study, we will compare how many HIV infections occurred in those who took TDF/FTC and those who took placebo when they didn't use condoms or didn't use them correctly.