AFRICA: New study of HIV prevention

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An international study aimed at establishing if it is possible to reduce a woman's risk of acquiring HIV using a vaginal gel or an oral tablet containing an antiretroviral drug, has been launched at the University of Zimbabwe.

The Spilhaus Clinical Research Site at the University of Zimbabwe, together with the Clinical Trials Unit at the University of California, San Francisco, began enrolling trial participants in Zimbabwe in September for the Vagina and Oral Interventions to Control the Epidemic Study, known as VOICE.

The large-scale clinical trial will take place at 14 sites in six cities in the four countries: seven sites in Durban and a single site each in Johannesburg and Klerksdorp in South Africa; three sites in Hararein Zimbabwe; a site in Kampala in Uganda; and a site in Lusaka in Zambia. Pending government approval, trials might also be conducted in Malawi.

The study will help to determine whether applying a vaginal microbicide gel containing an antiretroviral (ARV) every day, or taking an oral ARV tablet once a day, can reduce a woman's risk of being infected by the HIV virus, the **MTN statement** said.

"While the study's primary aim is to evaluate the safety and effectiveness of the two regimens, an important question VOICE will also address is which of the two - the tablet or the gel - women will actually be more inclined to use. It is the first HIV prevention trial testing these two different approaches in the same study and the first effectiveness trial of a microbicide in which women use the gel every day instead of only at the time of sex."

Nearly 60% of adults living with HIV in Sub-Saharan Africa are women, and in several southern African countries young women are at least three times more likely to be HIV-positive than young men. In most cases, women acquire HIV through sexual intercourse with an infected male partner, the statement said.

The study's co-chairs are Jeanne Marrazzo, associate professor of medicine in the division of allergy and infectious diseases at the University of Washington in Seattle, and Professor Mike Chirenje of the department of obstetrics and gynaecology at the University of Zimbabwe.

Chirenje said: "The HIV prevention field has not been without its share of disappointments and so, naturally, we are excited that in VOICE we have not just one but two promising approaches to evaluate. Hopefully, we'll find that ARVs, which helped turn the tide in the treatment of HIV, can be a prevention powerhouse too."

Two ARV tablets are being tested in the VOICE Study: tenofovir and Truvada. The tablets will be taken prior to exposure in an approach known as pre-exposure prophylaxis, or PrEP. The vaginal microbicide being evaluated is tenofovir topical gel. Testing a microbicide and PrEP in the same trial will enable scientists to directly compare the two strategies in terms of their safety and acceptability.

The network said all participants - sexually active, HIV-uninfected women between the ages 18 and 45 - will receive regular HIV testing and risk-reduction counselling, condoms, and testing for sexually transmitted infections or STIs. Any participant who acquires HIV or an STI during the study will be referred to treatment and care in her community.

MTN is an HIV-Aids clinical trials network set up in 2006 by the National Institute of Allergy and Infectious Diseases in the US. Based at the University of Pittsburgh and the Magee-Women's Research Institute, it brings together researchers and community and industry partners devoted to preventing or reducing the sexual transmission of HIV.

The study is being funded by the national institute, with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health in the US.