

FACTS 001 – Tenofovir Gel Study

Young women bear the brunt of the HIV epidemic in southern Africa. In the recent clinical trial, CAPRISA 004, tenofovir gel was observed to be 39% effective in preventing HIV infection in women. The reduction in risk reached 54% among women who reported using the product most consistently. It is estimated that such an intervention with this effectiveness could prevent 1.3 million HIV infections over 20 years in South Africa alone. The study also demonstrated a reduction in the risk of becoming infected with the Herpes Simplex Virus 2 (HSV-2) by 51%. The CAPRISA study was a small study designed to show proof of concept that the gel could protect against HIV, but the study was not large enough on its own to support registration of the product. There is therefore an urgent need to repeat the CAPRISA tenofovir gel study, and conducting a confirmatory trial is an essential component on the path to licensure and public health implementation.

FACTS is a newly-created South African initiated and led consortium established to develop and conduct follow-on research, primarily a Phase III placebo-controlled safety and effectiveness study, to test whether tenofovir gel can protect women against HIV infection and also against infection with herpes. If this study confirms the findings of the CAPRISA 004 study, these combined data could enable licensure of this microbicide product and hence make available to women the first women-controlled HIV prevention method. Professor Helen Rees is the Protocol Chair for FACTS 001 and Professors Glenda Gray and Gita Ramjee are the co-chairs for the study. FACTS is being supported by the Minister of Health and the Deputy Minister of Science and Technology.

The proposed FACTS 001 tenofovir gel study

- Will enrol 3,150 HIV-negative, sexually active women aged 16 - 30 years old
- Will enrol participants at 7 sites around South Africa (discussions are underway to include an additional site in Kenya to expand generalisability)
- Will duplicate the dosing used in CAPRISA 004, where women inserted one gel within 12 hours before and one gel within 12 hours after sex with no more than two gels in a 24-hour period (known as the BAT24 dosing strategy)
- Will provide safety data in younger women aged 16-17 (a critical data gap)
- Will investigate the effectiveness of tenofovir gel against Herpes Virus 2
- Will investigate the safety of the gel when used by women infected with Hepatitis B
- Will investigate the acceptability of the gel with women and examine how they choose to use the product
- Will be designed so that the South African sites will enrol enough participants to answer the research question, but data generated by the Kenyan site can be jointly analysed with the South African data
- Will begin enrolment in mid-2011, complete participant follow-up by June 2013 and release results by end of 2013

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