

What is CAPRISA 004?

CAPRISA 004 was a phase IIb, two-arm, double-blind, randomised, placebo-controlled trial designed to assess the safety and effectiveness of the vaginal microbicide candidate 1% tenofovir gel for the prevention of HIV infection in women in South Africa.

The CAPRISA 004 trial tested a microbicide gel that contained a drug called tenofovir. Tenofovir is an anti-retroviral (ARV) drug that is used as an oral treatment for HIV in many countries and is licensed for use as HIV treatment in South Africa. CAPRISA 004 is the first trial to evaluate an ARV-based candidate microbicide gel for the prevention of sexually transmitted HIV infection among women. The trial commenced enrolment in May 2007 and completed follow-up in December 2009. The results of the trial will be released at the International AIDS Conference in Vienna, Austria, on Tuesday 20 July 2010.

The CAPRISA 004 trial was conducted at two CAPRISA (Centre for the AIDS Programme of Research in South Africa) clinical research sites in the KwaZulu-Natal Province of South Africa: in an urban area of eThekweni (Durban) and a rural area of Vulindlela (Pietermaritzburg).

The CAPRISA 004 trial enrolled 889 South African women who were 18 to 40 years of age, HIV-negative, sexually active, and at high risk of becoming infected with HIV. Women in the trial were asked to vaginally insert a first dose of tenofovir gel no more than 12 hours before having sex and to insert a second dose no more than 12 hours after having sex. No more than 2 doses of gel were used in a 24-hour period, even if the women had sex more than once.

CAPRISA 004 was a relatively small trial (called a phase IIb trial) as it was designed to explore whether tenofovir gel was a promising microbicide candidate. It was not designed to provide sufficient evidence to licence a new drug (which would generally require a definitive phase III trial).

The CAPRISA 004 trial measured whether tenofovir gel reduced the risk of HIV infection among women provided with the tenofovir gel compared to women provided with a placebo gel. All participants received regular HIV risk-reduction counselling, condoms, and treatment of symptomatic sexually transmitted infections, if required.

The CAPRISA 004 trial also measured whether tenofovir gel was safe to use regularly over a longer period of time than had previously been assessed in clinical safety studies. Women in the trial typically used the gel for 12 to 18 months. The trial systematically collected information on all health complications, genital events, and systemic toxicity (if the drug reached the blood stream).

The CAPRISA 004 trial also assessed if women who sero-converted during the trial developed resistance to tenofovir and the effect that using tenofovir gel for HIV prevention had on the HIV viral load after sero-conversion.

The trial was conducted by a consortium that included the Centre for the AIDS Programme of Research in South Africa (CAPRISA) at the University of KwaZulu-Natal in Durban; FHI, North Carolina, USA; and CONRAD, Virginia, USA. It was funded by the United States Agency for International Development (USAID) and TIA, a biotechnology agency of the South African government's Department of Science and Technology. In addition, Gilead Sciences provided tenofovir for the manufacture of the gel used in the study.

For more information, visit <http://www.global-campaign.org/CAPRISA004.htm>



Expanding HIV prevention options, especially for women
www.global-campaign.org

