

BIOMEDICAL HIV PREVENTION RESEARCH: A COMPREHENSIVE TIMELINE OF EFFICACY TRIAL RESULTS*

2007	2008	2009	2010	2011	2012+
<p>CONRAD CELLULOSE SULFATE Phase III trial to evaluate the effect of cellulose sulfate gel on vaginal HIV transmission in women (Benin, India, South Africa, Uganda, Zimbabwe) <i>Trial stopped early. No evidence of benefit. There were more infections among women using the gel than those using placebo, but this was not statistically significant.</i></p>	<p>HSV-2 SUPPRESSION (HPTN 039) Phase III trial to evaluate suppressive acyclovir treatment for the reduction of HIV infection in HSV-2 seropositive women and men who have sex with men (Peru, South Africa, US, Zambia, Zimbabwe) <i>No evidence of benefit.</i></p>	<p>HPTN 035 Phase II/III trial to evaluate the safety and effectiveness of the vaginal microbicides, BufferGel and 0.5% PRO 2000/5 gel, to prevent HIV infection in women (Malawi, South Africa, US, Zambia, Zimbabwe) <i>There were fewer infections in women using PRO 2000 than women using the placebo gel, but this difference was not statistically significant. No evidence of benefit in women using BufferGel.</i></p>	<p>CDC 4323 Phase II trial to evaluate the clinical and behavioral safety of once-daily oral TDF among men who have sex with men (US) <i>Release of results expected February 2010.</i></p>	<p>iPrEx Phase III trial to evaluate the safety and efficacy of once-daily oral TDF/FTC to prevent HIV infection among men who have sex with men (Brazil, Ecuador, Peru, South Africa, Thailand, US)</p>	<p>PARTNERS PrEP Phase III trial to evaluate the safety and efficacy of two different strategies to prevent HIV transmission in HIV-serodiscordant couples: once-daily oral TDF and once-daily oral TDF/FTC (Kenya, Uganda)</p>
<p>FHI CELLULOSE SULFATE Phase III trial to evaluate the safety and effectiveness of cellulose sulfate gel to prevent HIV infection in women (Nigeria) <i>Trial stopped following announcement of data from CONRAD trial. No evidence of safety concerns or of effectiveness.</i></p>	<p>MALE CIRCUMCISION IN HIV-POSITIVE MEN Large-scale trial to evaluate the safety of male circumcision and its potential protective effect for HIV-negative female partners of HIV-positive circumcised males (Uganda) <i>Trial stopped enrollment, December 2006. No statistically significant conclusions could be drawn from sample size. However, men who resumed sex prior to wound healing were more likely to transmit HIV to their female partners.</i></p>	<p>PARTNERS IN PREVENTION Phase III study to evaluate the effect of suppressive acyclovir treatment for HSV-2 on HIV transmission in HIV-serodiscordant couples (Botswana, Kenya, Rwanda, South Africa, Tanzania, Uganda, Zambia) <i>No evidence of reduced rates of HIV transmission, but there were reduced rates of genital ulcers and HIV viral load.</i></p>	<p>CAPRISA 004 Phase IIb trial to evaluate the safety and effectiveness of 1% tenofovir gel to prevent HIV infection in women (South Africa) <i>Release of results expected July 2010.</i></p>		<p>FEM-PrEP Phase III trial to evaluate the safety and effectiveness of once-daily oral TDF/FTC for HIV prevention in women (Kenya, Malawi, South Africa, Tanzania, Zambia)</p>
<p>MIRA Phase III trial to evaluate effectiveness of the female diaphragm to prevent HIV infection (South Africa, Zimbabwe) <i>No evidence of benefit.</i></p>	<p>CARRAGUARD Phase III trial to evaluate the safety and efficacy of the vaginal microbicide Carraguard to prevent HIV infection in women (South Africa) <i>No evidence of benefit.</i></p>	<p>ALVAC-AIDSVAX (RV 144) Phase III trial to evaluate the safety and efficacy of a prime-boost vaccine strategy (ALVAC plus AIDSVAX) to prevent HIV infection (Thailand) <i>Initial data show that vaccine recipients were 31% less likely than placebo recipients to become HIV-infected. There was no observed effect on viral load. Additional data analysis is ongoing.</i></p>	<p>CDC 4370 Phase II/III trial to evaluate the safety and efficacy of once-daily oral TDF to prevent HIV infection in injecting drug users (Thailand)</p>		<p>HVTN 505 Phase II test-of-concept trial to evaluate the safety and effect on post-HIV infection viral load of the VRC's DNA prime / Ad5-boost vaccine strategy in HIV-negative, Ad5-seronegative and circumcised men who have sex with men (US)</p>
<p>STEP (HVTN 502/Merck 023) Phase IIb test-of-concept trial to evaluate safety and efficacy of Merck's Ad5 candidate (Australia, Brazil, Canada, Dom. Rep., Haiti, Jamaica, Peru, Puerto Rico, US) <i>Trial halted immunizations, September 2007. Data analysis found no evidence of benefit and potential for increased risk of HIV infection among Ad5-seropositive, uncircumcised men; follow-up continues.</i></p>		<p>MDP 301 Phase III trial to evaluate the safety and efficacy of the 0.5% PRO 2000/5 to prevent HIV infection in women (South Africa, Tanzania, Uganda, Zambia) <i>No evidence of benefit.</i></p>	<p>CDC 4940 (TDF2) Phase II trial to evaluate the safety of once-daily oral TDF/FTC in heterosexual men and women (Botswana)</p>		<p>VOICE (MTN-003) Phase IIb trial to evaluate the safety and effectiveness of three different strategies to prevent HIV in women: once-daily oral TDF, once-daily oral TDF/FTC, and 1% tenofovir gel (South Africa, Uganda, Zambia, Zimbabwe)</p>
<p>PHAMBILI (HVTN 503) Phase IIb test-of-concept trial to evaluate the safety and efficacy of Merck's Ad5 candidate (South Africa) <i>Trial halted enrollment and immunizations, following Step; follow-up continues.</i></p>					<p>HPTN 052 Phase III trial to evaluate the effectiveness of two antiretroviral treatment strategies to prevent HIV transmission in HIV-serodiscordant couples (Botswana, Brazil, India, Kenya, Malawi, South Africa, Thailand, US, Zimbabwe)</p>

■ VACCINE
■ MICROBICIDE
■ PRE-EXPOSURE PROPHYLAXIS (PrEP)
■ PARTNER TREATMENT
■ HERPES SIMPLEX VIRUS 2 (HSV-2) TREATMENT/SUPPRESSION
■ MALE CIRCUMCISION
■ CERVICAL BARRIER METHOD
 TRIAL COMPLETED OR STOPPED

To view this timeline online with trial details please visit www.avac.org/timeline-website/.

Trials listed here are subject to interim analyses throughout the length of the trial.

* The trial end-dates listed in this table are estimates. Due to the nature of clinical trials the actual dates may change.