

## 2007

**Trial:** Phase 3 Study of the Efficacy and Safety of the Microbicide Carraguard® in Preventing HIV Seroconversion in Women

**Rationale:** The overall rationale for all microbicide trials is to identify products which could be used vaginally or rectally to help reduce the risk of HIV infection in the user. These products could take a number of forms including gels, suppositories and creams; they could be initiated and used by women. Carraguard® is a candidate derived from a seaweed called carrageenan. It has been extensively tested for safety in small animals and humans with no serious adverse events.

**Study Questions:** Carraguard® is currently being evaluated in a Phase III efficacy trial which is designed to determine whether it can protect women against HIV if it is used consistently and correctly before sex; if it is safe for use; and whether correct and consistent gel use reduces risk of infection with other sexually transmitted infections.

**Who's involved:** 6,299 HIV-uninfected women

**Where:** multiple sites in South Africa

**Trial sponsors and collaborators:** Population Council, Gates Foundation, USAID

**When can we expect results?** Late-2007, early-2008

**To learn more visit:**

- <http://www.popcouncil.org/microbicides/index.html>
  - <http://www.clinicaltrials.gov/ct/show/NCT00213083>
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**Results announced July 2007.**

**[Click here for more information on the trial from the Cervical Barrier Advancement Society..](#)**

**Trial:** The Latex Diaphragm To Prevent HIV Acquisition Among Women: A Female-Controlled Physical Barrier Of The Cervix or "Methods for Improving Reproductive Health in Africa" (MIRA)

**Rationale:** Some cell types found in the cervix (the opening to the uterus) are highly susceptible to HIV infection. HIV can infect a number of cell types found in womens' genital tracts. However, the cells of the cervix might be an important target. To test this hypothesis, the MIRA trial is looking at whether the use of the contraceptive diaphragm, which covers the cervix, reduces the risk of HIV infection in women during vaginal sex.

**Study Questions:** This ongoing study measures the effectiveness of the Ortho All-Flex® diaphragm used with Replens® lubricant gel in reducing risk of HIV infection among women at high risk.

**Who's involved:** 4,500 at-risk HIV-uninfected women

**Where:** South Africa and Zimbabwe

**Trial sponsors and collaborators:** University of California at San Francisco, Bill & Melinda Gates Foundation

**When can we expect results?** Mid-late 2007

**To learn more visit:**

- <http://www.uz-ucsf.co.zw/research/researchprojects/current/mira.html>
  - <http://cidea.ucsf.edu/mira.html>
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**Trial:** Randomized Controlled Trial of Cellulose Sulfate Gel and HIV in Nigeria

**Rationale:** The overall rationale for all microbicide trials is to identify products which could be used vaginally or rectally to help reduce the risk of HIV infection in the user. These products could take a number of forms including gels, suppositories and creams; they could be initiated and used by women. Cellulose sulfate is an HIV entry inhibitor.

**Study Questions:** The study was designed to assess the impact of correct and consistent CS use on rates of HIV infection and infection with other sexually transmitted infections among at-risk women.

**Who's involved:** 2,160 HIV-uninfected women at high risk for HIV infection

**Where:** Nigeria

**Trial sponsors and collaborators:** Family Health International, USAID, CONRAD

**When can we expect results?** Trial stopped early by Data Safety and Monitoring Board, January 2007 - [click here for more information](#)

**To learn more visit:**

- <http://www.clinicaltrials.gov/show/NCT00120770>
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**Trial:** Randomized Controlled Trial of 6% Cellulose Sulfate Gel and the Effect on Vaginal HIV Transmission

**Rationale:** The overall rationale for all microbicide trials is to identify products which could be used vaginally or rectally to help reduce the risk of HIV infection in the user. These products could take a number of forms including gels, suppositories and creams; they could be initiated and used by women. Cellulose sulfate is an HIV entry inhibitor.

**Study Questions:** The study was designed to assess the impact of correct and consistent CS use on rates of HIV infection and infection with other sexually transmitted infections among at-risk women.

**Who's involved:** 2,574 HIV-uninfected women at high-risk of heterosexual STI infection

**Where:** Benin, India, South Africa, Uganda and Zimbabwe

**Trial sponsors and collaborators:** CONRAD, USAID, Bill & Melinda Gates Foundation

**When can we expect results?** Trial stopped early by Data Safety and Monitoring Board, January 2007 - [click here for more information](#)

**To learn more visit:**

- <http://www.clinicaltrials.gov/ct/show/NCT00153777>
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## 2008

**Trial:** A Phase III, randomized, double-blind, placebo-controlled trial of acyclovir for the reduction of HIV acquisition among high risk HSV-2 seropositive, HIV-seronegative individuals.

**Rationale:** The presence of genital ulcers caused by herpes simplex virus type 2, or HSV-2, has been suggested as a possible risk factor for becoming infected with HIV. However, observations like these need to be confirmed in clinical trials. This study tests the hypothesis that untreated HSV-2 infection enhances an individual's risk of becoming infected with HIV.

**Study Questions:** This study is a randomized trial designed to answer the question: Does treating and preventing outbreaks of HSV-2 related genital ulcers in people who have HSV-2 and *do not* have HIV reduce their risk of becoming infected with HIV?

**Who's involved:** A total of 2,820 women who have sex with men and men who have sex with men

**Where:** Zambia, South Africa, Zimbabwe, Peru, USA

**Trial sponsors and collaborators:** University of Washington, US National Institutes of Health

**When can we expect results?** 2008

**To learn more visit:**

- [http://www.hptn.org/research\\_studies/hptn039.asp](http://www.hptn.org/research_studies/hptn039.asp)
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**Trial:** Project UNITY is a randomized trial which compares enhanced HIV risk reduction and vaccine education interventions with standard interventions currently used in vaccine trials.

**Rationale:** HIV prevention research including vaccine trials have generated a wealth of experience in offering high quality risk reduction counseling. However there have been very few attempts to systematically evaluate various forms of counseling in terms of their impact on comprehension of key concepts and/or rates of various risk behavior. This trial is enrolling HIV-negative, high-risk women who use non-injection drugs and is measuring the impact of both interventions on sexual risk behavior (unprotected vaginal and anal sex acts) and knowledge and understanding of vaccine trials and of a potential HIV vaccine. In lieu of an experimental vaccine, all participants are all offered hepatitis B immunization.

This trial is designed to find more about the best approaches to prevention standard of care for this specific population. It is the type of research that can be used to enhance and explain the standards of prevention offered in the context of AIDS prevention trials.

**Study Questions:** Specifically, the trial will ask: Does an enhanced approach to vaccine education and risk reduction counseling (using videos, client-initiated goals, and other innovative strategies) lead to greater comprehension of vaccine concepts and/or greater reductions in HIV risk behavior compared to standard approach similar to what is generally employed?

**Who's involved:** 400 HIV-negative high-risk, non-pregnant women who use non-injection drugs

**Where:** New York, NY

**Trial sponsors and collaborators:** New York Blood Center, The New York Academy of Medicine, Rutgers University

**When can we expect results?** 2008

**To learn more visit:**

- <http://www.clinicaltrials.gov/ct/show/NCT00150098>
  - <http://www.projectachieve.org/studies/new.html>
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**Trial:** Study of the Safety and Efficacy of Daily Tenofovir-Disoproxil Fumarate (TDF) to Prevent HIV Infection Among Injection Drug Users in Bangkok, Thailand

**Rationale:** Antiretrovirals may prevent HIV infection in HIV-uninfected individuals by disabling or interfering with HIV during the initial period after an individual is exposed. The use of ARVs to prevent mother-to-child-transmission and for *post*-exposure prophylaxis (in health workers and rape survivors for example) provides supportive evidence for this approach. Studies in non-

human primates have shown that giving ARVs *before* exposure can help block infection. This approach, which is known as pre-exposure prophylaxis, would involve the use of ARVs people who are HIV-uninfected to help reduce their risk of acquiring HIV.

**Study questions:** This study is being conducted to examine the safety and efficacy of a pre-exposure prophylaxis strategy (once-daily tenofovir) in injection drug users. The trial is designed to determine whether regular use of tenofovir is safe, and whether it reduces the risk of HIV acquisition in people whose primary risk factor is injection drug use.

**Who's involved:** 1,600 HIV-uninfected injecting drug users (IDUs)

**Where:** Thailand

**Trial sponsors and collaborators:** CDC

**When can we expect results?** 2008

**To learn more visit:**

- <http://www.cdc.gov/hiv/resources/factsheets/prep.htm>
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**Trial:** Phase III Randomized Placebo-Controlled Trial of HSV-2 Suppression to Prevent HIV Transmission Among HIV Sero-Discordant Couples

**Rationale:** Infection with and/or the presence of genital ulcers caused by herpes simplex virus type 2, or HSV-2, in HIV-infected individuals has been suggested as a possible risk factor for transmission of HIV. There are many possible explanations for this observation, including that co-infection with HSV-2 has been linked to increased “viral shedding” of HIV in the genital tract. It is possible that treating HSV-2 in people with HIV could reduce their infectiousness to their partners.

**Study questions:** This study will test the hypothesis that treating HSV-2 infection in the HIV-infected partner of a serodiscordant heterosexual couple (a couple in which one partner has HIV and the other does not) will reduce the chances that he or she will transmit the HIV virus to the uninfected partner.

**Who's involved:** 3,000 HIV-serodiscordant heterosexual couples

**Where:** Botswana

**Trial sponsors and collaborators:** University of Washington, Bill & Melinda Gates Foundation

**When can we expect results?** 2009

**To learn more visit:**

- <http://www.clinicaltrials.gov/ct/show/NCT00197574>

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**Trial:** Trial of Male Circumcision: HIV, STD and Behavioral Effects in Men, Women and the Community

**Rationale:** Clinical studies have shown that aseptic adult male circumcision performed by trained personnel can reduce male risk of HIV infection via vaginal intercourse. (The men in these trials also received condoms, risk reduction counseling and diagnosis and treatment of sexually transmitted infections.) The studies which have been completed to date do not address the safety and efficacy of circumcision in HIV-infected men. It is important to determine whether the procedure is as safe for HIV-infected men and men who do not know their status as it is for HIV-uninfected men; and to determine whether the procedure has an impact on rates of HIV transmission from circumcised, HIV-infected men to their partners. These data will help guide public health policy and implementation strategies.

**Study Questions:** This study enrolled HIV-infected men and men who do not wish to know their status, and randomized them to receive immediate or delayed circumcision. Rates of adverse events and side effects are measured to determine whether they are comparable to those observed in HIV-uninfected men. Female partners of men who are enrolled in this study and the other circumcision trial were enrolled in the study to determine whether there is an impact on HIV transmission. The men and women were not enrolled as couples. They were recruited separately, preserving confidentiality about HIV status. The study was designed to detect a population-level impact on male-to-female HIV transmission.

**Who's involved:** 800 HIV-infected men and 1,000 men who decline to know their status and 5,000 women partners of men enrolled in the Ugandan male circumcision studies.

**Where:** Rakai, Uganda

**Trial sponsors and collaborators:** Johns Hopkins University, Rakai Health Sciences Project, Gates Foundation

**When can we expect results?** Enrollment and circumcisions halted in December 2006 following DSMB recommendation that the trial enrollment was not sufficient to achieve statistically significant results. Follow-up is ongoing; additional investigations are underway to further investigate early, insignificant data suggesting possible increase risk of transmission from newly-circumcised men to female partners.

**To learn more visit:**

- <http://www.clinicaltrials.gov/ct/show/NCT00124878>
- [Male Circumcision for HIV Prevention](#)

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**2009**

**Trial:** Test-of-concept study of adenovirus preventive HIV vaccine candidate (Step study or HVTN 502)

**Rationale:** Vector is the scientific term for a carrier, such as disabled and harmless virus, which is used to convey an [immunogen](#) into the body. Vectors are used in hopes of boosting the body's immune response to the immunogen. An experimental HIV vaccine which combines synthetic fragments of HIV genetic material with an adenovirus vector has been shown to cause high levels of HIV-specific immune responses in humans. As with all HIV vaccines, the fragments of HIV used in this candidate cannot cause illness or disease. The strength and breadth of the immune responses induced by the Ad5 candidate (MRK-Ad5) led scientists to launch a study designed to give a preliminary indication of whether this vaccine strategy can reduce the risk of HIV infection and/or blunt the severity of HIV disease in people who are vaccinated, and go on to acquire HIV.

**Study Questions:** Does immunization with Ad5 reduce the risk of HIV infection via sexual transmission? Do people who are immunized with Ad5 and go on to become infected with HIV have a lower viral set point than people who received the placebo and later became infected? The trial will also gather information on safety to confirm and expand on earlier findings which showed that the candidate is safe for use in humans.

It is important to note that this trial will only provide a preliminary answer about whether Ad5 is an effective strategy. Statisticians have designed the trial so that final data analysis can show whether there is a likely impact; this will need to be followed up and confirmed in additional trials.

**Who's involved:** 3,000 HIV-uninfected men and women

**Where:** Australia, Brazil, Canada, Dominican Republic, Haiti, Jamaica, Peru, Puerto Rico, United States

**Trial sponsors and collaborators:** Merck, NIH, HVTN

**When can we expect results?** Trial stopped early, September 2007. For more information visit [http://avac.org/pr\\_step\\_study.htm](http://avac.org/pr_step_study.htm).

**To learn more visit:**

- <http://www.hvtn.org/science/step.html>
- [http://www.stepstudies.com/about\\_step.html](http://www.stepstudies.com/about_step.html)

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**Trial:** Phase II/IIb Safety and Effectiveness Study of the Vaginal Microbicides BufferGel and 0.5% PRO 2000/5 Gel (P) for the Prevention of HIV Infection in Women

**Rationale:** The overall rationale for all microbicide trials is to identify products which could be used vaginally or rectally to help reduce the risk of HIV infection in the user. These products could take a number of forms including gels, suppositories and creams; they could be initiated

and used by women. BufferGel is a buffering agent designed to maintain normal vaginal acidity in the presence of ejaculate. Studies have shown that HIV is inactivated below a pH of 4 to 5.8, so this kind of candidate could block viral activity.

**Study Questions:** This study will evaluate the safety and effectiveness of these two vaginal microbicides in preventing the transmission of HIV. The study will also evaluate the effectiveness of these gels in preventing other common sexually transmitted infections (STIs).

**Who's involved:** 3,220 HIV-uninfected women

**Where:** Malawi, South Africa, Tanzania, Zambia, Zimbabwe, United States

**Trial sponsors and collaborators:** NIH-NIAID, Indevus, ReProtect

**When can we expect results?** 2009

**To learn more visit:**

- <http://www.clinicaltrials.gov/show/NCT00074425>
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**Trial:** A Phase III Trial of Aventis Pasteur Live Recombinant ALVAC-HIV (vCP1521) priming With VaxGen gp120 B/E (AIDSVAX B/E) boosting in HIV-Uninfected Thai Adults

**Rationale:** This trial tests a combination of two vaccine candidates in what is known as a 'prime-boost' strategy. The general rationale for the prime-boost approach is that using a sequence of two different vaccines may lead to stronger and broader immune responses than multiple immunizations of the same vaccine. The vaccines in this strategy are called ALVAC-HIV (vCP1521), which is given as the 'prime' vaccine and AIDSVAX gp120 B/E, which is given as the 'boost'. AIDSVAX has been tested on its own in two previous efficacy trials and was found to have no effect on rates of HIV infection. It has not been tested in combination.

**Study Questions:** Is a prime-boost vaccine combination safe and effective at reducing rates of HIV infection in men and women whose primary risk factor for HIV is sexual exposure?

**Who's involved:** 16,402 HIV-uninfected healthy adults

**Where:** Thailand

**Trial sponsors and collaborators:** Thailand Ministry of Public Health, Thai AIDS Vaccine Evaluation Group, U.S. Military HIV Research Program

**When can we expect results?** 2010

**To learn more visit:**

- <http://www.clinicaltrials.gov/ct/show/NCT00223080>
- [http://www.primeboost3.org/index\\_eng.htm](http://www.primeboost3.org/index_eng.htm)

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**Trial:** An International Multi-Centre, Randomised, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of 0.5% and 2% PRO 2000/5 Gels for the Prevention of Vaginally Acquired HIV Infection

**Rationale:** The overall rationale for all microbicide trials is to identify products which could be used vaginally or rectally to help reduce the risk of HIV infection in the user. These products could take a number of forms including gels, suppositories and creams; they could be initiated and used by women. PRO2000/5 (Indevus) is a sulphonated polymer which may block HIV from binding to cells in the vagina. This study is looking at two strengths of PRO 2000 (0.5%, and 2.0%) versus placebo.

**Study Questions:** The objective of the study is to determine the efficacy and safety of 0.5% and 2% PRO 2000/5 gels compared to placebo in preventing vaginally acquired HIV infection.

**Who's involved:** 9,673 sexually active, HIV-uninfected women

**Where:** South Africa, Tanzania, Uganda

**Trial sponsors and collaborators:** Indevus, MRC, DFID

**When can we expect results?** 2009

**To learn more visit:**

- <http://www.clinicaltrials.gov/ct/gui/show/NCT00262106?order=5>
- <http://www.mdp.mrc.ac.uk/clinical.html>

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**Trial:** Phase 2 Extended Safety Study of Tenofovir-Disoproxil Fumarate (TDF) among HIV-1 Negative Men

**Rationale:** Antiretrovirals may prevent HIV infection in HIV-uninfected individuals by disabling or interfering with HIV during the initial period after an individual is exposed. The use of ARVs to prevent mother-to-child-transmission and for post-exposure prophylaxis provides supportive evidence for this approach. Studies in non-human primates have shown that giving ARVs *before* exposure can help block infection. This approach, which is known as pre-exposure prophylaxis, would involve the use of ARVs people who are HIV-uninfected to help reduce their risk of acquiring HIV.

**Study questions:** This trial is designed to determine the clinical and behavioral safety of a pre-exposure prophylaxis strategy (once-daily tenofovir) in HIV-negative men who have sex with men.

**Who's involved:** 400 HIV-uninfected MSM

**Where:** San Francisco, Atlanta and Boston, USA

**Trial sponsors and collaborators:** CDC

**When can we expect results?** 2009

**To learn more visit:**

- <http://www.cdc.gov/hiv/resources/factsheets/prep.htm>
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**Trial:** Study of the Safety and Efficacy of Daily Tenofovir Disoproxil Fumarate and Emtricitabine (Truvada®) for the Prevention of HIV Infection in Heterosexually Active Young Adults in Botswana

**Rationale:** Antiretrovirals may prevent HIV infection in HIV-uninfected individuals by disabling or interfering with HIV during the initial period after an individual is exposed. The use of ARVs to prevent mother-to-child-transmission and for *post*-exposure prophylaxis provides supportive evidence for this approach. Studies in non-human primates have shown that giving ARVs *before* exposure can help block infection. This approach, which is known as pre-exposure prophylaxis, would involve the use of ARVs people who are HIV-uninfected to help reduce their risk of acquiring HIV.

**Study questions:** This study is being conducted examine the safety and efficacy of a pre-exposure prophylaxis strategy (once-daily Truvada®, a combination of the drugs tenofovir and emtricitabine) in reducing the risk of HIV infection in serodiscordant couples whose primary risk factor is vaginal sex.

**Who's involved:** 1,200 HIV-uninfected heterosexual men and women

**Where:** Botswana

**Trial sponsors and collaborators:** CDC

**When can we expect results?** 2009

**To learn more visit:**

- <http://www.cdc.gov/hiv/resources/factsheets/prep.htm>
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## 2010

**Trial:** Chemoprophylaxis for HIV Prevention in Men

**Rationale:** Antiretrovirals may prevent HIV infection in HIV-uninfected individuals by disabling or interfering with HIV during the initial period after an individual is exposed. The use of ARVs

to prevent mother-to-child-transmission and for post-exposure prophylaxis provides supportive evidence for this approach. Studies in non-human primates have shown that giving ARVs *before* exposure can help block infection. This approach, which is known as pre-exposure prophylaxis, would involve the use of ARVs people who are HIV-uninfected to help reduce their risk of acquiring HIV.

**Study Questions:** The purpose of this study is to evaluate the safety and effectiveness of daily Truvada in preventing HIV transmission in HIV-1 uninfected men who have sex with men (MSM).

**Who's involved:** 3,000 high-risk MSM

**Where:** Peru, Ecuador, US and additional sites TBD

**Trial sponsors and collaborators:** NIAID

**When can we expect results?** 2010

**To learn more visit:**

- <http://www.clinicaltrials.gov/ct/show/NCT00350324?order=21>
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**Trial:** Safety and Effectiveness Study of a Candidate Vaginal Microbicide for Prevention of HIV

**Rationale:** The overall rationale for all microbicide trials is to identify products which could be used vaginally or rectally to help reduce the risk of HIV infection in the user. These products could take a number of forms including gels, suppositories and creams.

Tenofovir gel is a gel containing the antiretroviral drug tenofovir, a proven anti-HIV drug in its oral form. This third generation microbicide aims to work within cells to stop HIV from replicating. This study is looking at 1% tenofovir gel versus a placebo.

**Study Questions:** The objective of the study is to determine the safety and effectiveness of 1% tenofovir gel compared to placebo in preventing vaginally acquired HIV infection in sexually active women at risk for HIV infection in South Africa.

**Who's involved:** 980 sexually active, HIV-negative women

**Where:** South Africa

**Trial sponsors and collaborators:** Centre for the AIDS Programme of Research in South Africa (CAPRISA), Family Health International (FHI), United States Agency for International Development (USAID), CONRAD

**When can we expect results?** 2010

**To learn more visit:**

- <http://www.iom.edu/Object.File/Master/40/550/Abdool%20Karim,%20CAPRISA.pdf>
  - <http://clinicaltrials.gov/show/NCT00441298>
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## 2011

**Trial:** A Multicenter Double-Blind Randomized Placebo-Controlled Phase IIB Test-of-Concept Study to Evaluate the Safety and Efficacy of a Three-Dose Regimen of the Clade B-Based Merck Adenovirus Serotype 5 HIV-1 Gag/Pol/Nef Vaccine in HIV-1 Uninfected Adults in South Africa

**Rationale:** Vector is the scientific term for a carrier, such as disabled and harmless virus, which is used to convey an immunogen into the body. Vectors are used in hopes of boosting the body's immune response to the immunogen. An experimental HIV vaccine which combines synthetic fragments of HIV genetic material with an adenovirus vector has been shown to cause high levels of HIV-specific immune responses in humans. As with all HIV vaccines, the fragments of HIV used in this candidate cannot cause illness or disease. The strength and breadth of the immune responses induced by the Ad5 candidate led scientists to launch a study designed to give a preliminary indication of whether this vaccine strategy can reduce the risk of HIV infection and/or blunt the severity of HIV disease in people who are vaccinated, and go on to acquire HIV.

**Study Questions:** Does immunization with Ad5 reduce the risk of HIV infection via sexual transmission? Do people who are immunized with Ad5 and go on to become infected with HIV have a lower viral set point than people who received the placebo and later became infected? The trial will also gather information on safety to confirm and expand on earlier findings which showed that the candidate is safe for use in humans.

It is important to note that this trial will only provide a preliminary answer about whether Ad5 is an effective strategy. Statisticians have designed the trial so that final data analysis can show whether there is a likely impact; this will need to be followed up and confirmed in additional trials.

**Who's involved:** 3000 HIV-uninfected men and women

**Where:** South Africa

**Trial sponsors and collaborators:** Merck Research Laboratories, NIH, HVTN, SAAVI

**When can we expect results?** Trial stopped early, September 2007. For more information visit [http://avac.org/pr\\_step\\_study.htm](http://avac.org/pr_step_study.htm).

**To learn more visit:**

- <http://www.saavi.org.za/1press2007.htm>
- <http://www.clinicaltrials.gov/ct/show/NCT00413725?order=8>

- [http://www.hvtm.org/faq/503/HVTN503FAQ\\_eng.pdf](http://www.hvtm.org/faq/503/HVTN503FAQ_eng.pdf)
- 

**Trial:** Phase III Randomized Controlled Trial of Community Mobilization, Mobile Testing, Same-Day Results, and Post-Test Support for HIV in Sub-Saharan Africa and Thailand

**Rationale:** Voluntary counseling and testing (VCT) is a critical entry point for AIDS care and prevention services. Public health experts have also suggested that the presence of VCT services in a community may help reduce rates of HIV transmission, since people may change their behaviors and take steps to protect themselves when they know their status --although this has not been clearly verified. Also, few studies have looked at how different approaches to VCT and related services impact on HIV incidence (rates of new infection). This is the first randomized controlled Phase III trial to determine the efficacy of a behavioral/social science intervention with an HIV incidence endpoint in the developing world.

**Study Questions:** This trial randomizes otherwise comparable communities to receive two different types of social-behavioral interventions. In one arm, communities will receive standard clinic-based VCT services. In the other, communities will receive an enhanced intervention which includes community-based VCT, mobilization and post-test support. The trial is designed to determine whether there is any difference in HIV incidence between communities receiving the two different interventions.

**Who's involved:** 34 communities in Africa and 14 communities in Thailand will be randomized to either the community-based HIV voluntary counseling and testing intervention or the clinic-based standard VCT

**Where:** Tanzania, Zimbabwe, South Africa, Thailand

**Trial sponsors and collaborators:** University of California at San Francisco, University of Zimbabwe, Johns Hopkins University, National Institute of Mental Health

**When can we expect results?** 2008

**To learn more visit:**

- <http://www.caps.ucsf.edu/research/portfolio/2006/Intl14.pdf>
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## 2013

**Trial:** Phase III, two-arm, multi-site, randomized trial to determine the effectiveness of two treatment strategies in preventing the sexual transmission of HIV in HIV-serodiscordant couples

**Rationale:** Based on data collected in Africa and Thailand, there is a correlation between HIV viral load (blood levels) and HIV transmission. Specifically, the higher the viral load in the blood, the more likely the chance for transmission. Antiretroviral therapy (ART) reduces the

viral load in the blood, as well as in genital secretions (for both men and women), and the drugs can be detected in semen and vaginal and cervical secretions.

**Study Questions:** Can antiretroviral therapy (ART) prevent the sexual transmission of HIV-1 in HIV-1 serodiscordant couples?

**Who's involved:** Approximately 1,750 HIV serodiscordant couples in which the HIV-infected partner is ART naïve and has a CD4+ cell count of 300-500 cells/mm<sup>3</sup>.

**Where:** Malawi, India, Zimbabwe, Brazil, Thailand, US

**Trial sponsors and collaborators:** NIH, GlaxoSmithKlein, Boehringer-Ingelheim

**When can we expect results?** 2013

**To learn more visit:**

- [http://www.hptn.org/research\\_studies/hptn052.asp](http://www.hptn.org/research_studies/hptn052.asp)