Ongoing HVTN Trials

Protocol	N	Trial Collaborators	Study Product(s)	Start Date*	Sites	Description
HVTN 076	17	HVTN VRC DAIDS	DNA multiclade rAd5 multiclade	September-11	Seattle	The study looks at the immune response of genital and rectal tissues to injections of a DNA vaccine followed by a recombinant adenovirus serotype 5 (rAd5) vaccine.
HVTN 082	8	HVTN VRC DAIDS	DNA multiclade rAd5 multiclade	June-10	Boston - Brigham; Boston – Fenway; Rochester; San Francisco; Seattle	The study looks at the role of genetics in determining immune responses to a DNA prime/rAd5 boost regimen. All study participants are twins.
HVTN 083	180	HVTN VRC DAIDS	rAD35 clade A rAd5 clade A rAd clade B	October-10	Atlanta – Hope Clinic; Birmingham; Boston - Brigham; Nashville; New York- Bronx Prevention; New York – Columbia; New York – Union Square; San Rochester; Francisco	This study looks at different vectors and inserts from different strains (clades) of HIV (made in the lab, not from real HIV), to see if different combinations of vectors and inserts increase the body's immune response.
HVTN 084	100	HVTN VRC DAIDS	rAd5 multiclade rAd5 clade B	March-11	Boston - Brigham; Chicago; Iquitos; Lausanne; Lima - Barranco; Sao Paulo; New York –Bronx Prevention, New York – Columbia; New York – Union Square	The study looks at whether the immune responses to 2 of the HIV genes (gag and pol) are affected by a study vaccine carrying 3 types of lab-made genes (gag, pol, and env) compared to a vaccine that contains only the gag and pol lab-made genes.
HVTN 085	90	HVTN VRC DAIDS	rAd5 multiclade	February-12	Boston; Chicago; Nashville; New York; Philadelphia; Rochester; San Francisco	Study looks at whether the immune response to the vaccine is improved if the vaccine is given all at once in one arm, or split into 4 injections in the arms and legs (for the same final dose as the single injection), or broken into its 4 component parts with each component given in a different arm or leg.

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HVTN 098	94	HVTN DAIDS Inovio	PENNVAX-GP IL-12 DNA adjuvant	September-15	Atlanta-Hope Clinic; Nashville; Rochester; Seattle	Study looks at the safety of a DNA vaccine given with an IL-12 plasmid DNA adjuvant and electroporation, given into the skin or into the muscle of the upper arm. It will also look at which approach results in stronger immune responses.
HVTN 100	252	HVTN BMGF GSK (formerly Novartis) SanofiPasteur DAIDS	ALVAC-HIV (vCP2438) [multiclade] Bivalent Subtype C gp120/MF59	February-15	Cape Town; Durban-eThekwini; Durban – Isipingo; Klerksdorp; Soshanguve; Soweto - Bara	HVTN 100 is evaluating the safety and immune responses to a vaccine regimen similar to the RV144 regimen in HIV-uninfected adults at low risk of HIV infection. The vaccines have been adapted to the southern African region by using clade C envelope antigens.: clade C ALVAC-HIV (vCP2438) and Bivalent Subtype C gp120/MF59®.
HVTN 105	104	HVTN BMGF IPPOX GSID USMHRP DAIDS	DNA clade C AIDSVAX® B/E (Subtypes B, E gp120)	July-14	New York- Physicians & Surgeons; Nashville; Philadelphia; Rochester; San Francisco; Seattle	The study tests 2 experimental HIV vaccines in different combinations, to see if these combinations result in different immune responses in the body. (The immune system helps a person fight infections).
HVTN 106	105	HVTN CHAVI-ID DAIDS EuroVacc LANL USMHRP	DNA multiclade MVA CRF01_AE	January-15	Atlanta-Hope Clinic; Birmingham; Boston-Brigham; Boston-Fenway; San Francisco; Seattle; Lausanne	The study tests 3 different experimental HIV DNA vaccines, to see if computer-generated DNA sequences for the HIV envelope will result in different immune responses compared to a natural HIV envelope gene. The Modified Vaccinia Ankara viral vector vaccine is used in the study to boost immune responses and enhance any differences between the 3 DNA vaccines.

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HVTN 110	60	HVTN PaxVax GSID USMHRP DAIDS	Ad4 multiclade AIDSVAX® B/E (Subtypes B, E gp120)	March-15	Atlanta-Hope Clinic; Birmingham; Boston-Brigham; Boston-Fenway; Cleveland; New York- Physicians & Surgeons; Nashville; New York-NYBC; Philadelphia; Rochester; San Francisco; Seattle	Study to test different combinations of 3 experimental HIV vaccines. Two of the study vaccines are given as a pill that people will swallow, and contain a live, weakened virus called adenovirus trype 4. The third vaccine is given as an injection. The study tests the safety of the combinations, and the immune responses of the body to the different combinations.
HVTN 111	132	HVTN DAIDS BMGF GSK (formerly Novartis) IPPOX	DNA Clade C Bivalent Subtype C gp120/MF59	May-16	Isipingo; Tembisa; Klerksdorp; Matero; Mbeya	The study tests 2 experimental HIV vaccines in different combinations, to see if these combinations result in different immune responses in the body. (The immune system helps a person fight infections). It also tests an injection device without needles that uses pressurized air to inject the vaccine, to see if this can improve the immune responses.
HVTN 112	15	HVTN DAIDS Profectus Ichor	DNA VSV envC	April-16	Cleveland; Philadelphia	Study looks at the safety of a DNA vaccine with a Clade B Env gene, given with electroporation into the deltoid muscle, followed by a recombinant vesicular stomatitis virus (rVSV) vaccine boost which has a Clade C Env gene. It will also look at the immune responses to the vaccines.
HVTN 404	Open	HVTN DAIDS	N/A	July-08	All sites	The primary purpose of this study is two-fold: 1) To follow participants who become HIV-1 infected after enrollment in early-phase vaccine clinical trials and vaccine preparedness studies; 2) To describe pretreatment HIV-1 RNA levels and CD4+ T-cell counts in vaccine and placebo recipients or vaccine preparedness study participants who become HIV-1 infected. To compare indications of disease progression in vaccinated and unvaccinated participants who become HIV-1

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						infected.
HVTN 505	2504	HVTN VRC DAIDS	DNA multiclade rAd5 multiclade	June-09	All US sites	This phase 2b study compares the rate of HIV infections and viral load in participants who become infected at Day 196 or later, comparing participants who received the vaccine regimen and those who received placebo.
HVTN 602	Open	Aeras SanofiPasteur Statens Serum Institut	H4:IC31 H56:IC31 BCG	July-15	Cape Town	A randomized, placebo-controlled, partially blinded phase 1b clinical trial to evaluate the safety and immunogenicity of BCG revaccination, H4:IC31, and H56:IC31 in healthy, HIV-1–uninfected adolescent participants
HVTN 703/HPTN 081	1500	HVTN HPTN DAIDS VRC	VRC01 mAb	May-16	Blantyre; Cape Town-Groote Schuur; Durban – Chatsworth; Durban – eThekwini; Gaborone; Harare – Parirenyatwa; Harare - Seke South; Harare – Spilhaus; Johannesburg -WRHI; Kisumu; Vulindlela; Lilongwe; Maputo; Mbeya; Soweto -Bara	This phase 2b study compares the rate of HIV infections in women who receive an infusion of an antibody against HIV (VRC01) and in women who receive the placebo infusion. The study also looks at the safety of these antibody infusions and it looks over time at how much antibody is in the blood of study participants receiving different amounts or doses of the antibody.
HVTN 704/HPTN 085	2700	HVTN HPTN DAIDS VRC	VRC01 mAb	April-16	Atlanta - Hope Clinic; Atlanta - Ponce de Leon; Birmingham; Boston – Brigham; Boston – Fenway; Chapel Hill; Cleveland; Columbia – Bronx Prevention; Columbia – Harlem Prevention;	This phase 2b study compares the rate of HIV infections in MSM and transgender individuals who receive an infusion of an antibody against HIV (VRC01) and in those who receive the placebo infusion. The study also looks at the safety of these antibody infusions and it looks over time at how much antibody is in the blood of study participants receiving different amounts or doses of the antibody.

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					Columbia – NYBC; Columbia - Physicians & Surgeons; Los Angeles – Vine Street; Nashville; Newark; Philadelphia; Rochester; San Francisco; Seattle; Washington, DC; Iquitos; Lima – Barranco; Lima - San Miguel; Lima – Via Libre	
HVTN 802	Open	HVTN DAIDS	N/A	September-09	All sites	The study follows participants in later phase HVTN trials who became HIV infected. This study looks at disease indicators (number of CD4+ T cells, viral load, etc.) before treatment and as the infection progresses. The study also compares the progression of HIV infections in people who received study products vs. those who did not.
HVTN 910	Open	HVTN DAIDS	N/A	December-11	All sites	The study follows participants who received a study vaccine in NIH-sponsored preventive HIV vaccine studies, and looks at how long vaccine-induced HIV antibodies, which are detectable on commercial test kits, last in these participants.

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