

Ongoing Trials of Preventive HIV Vaccines (page 1)

Last updated: September 29, 2004

Trial No.	Sponsor Manufacturer	Start Date	Sites (No.)	Vaccine	Antigen	Clade	Comment
Phase III (Large-size trials in high-risk populations; test vaccine efficacy)							
RV144	WRAIR, AFRIMS, MoH; Aventis, VaxGen	October 2003	Thailand (several)	ALVAC vCP1521 AIDSVAX B/E	env (E), gag/pol (B) env (B, E)	B, E B, E	16,000 healthy normal HIV negative adult volunteers
Phase II (Mid-size trials in low- & high-risk populations; test vaccine safety, immunogenicity)							
ANRS VAC 18	ANRS; Aventis	September 2004	France (6)	LIPO-5	5 lipopeptides containing CTL epitopes (from Gag, Pol, Nef)	B	Primary objective: To compare the cellular immunogenicity (CD8 response) of 3 doses of LIPO-5 versus placebo
IAVI 010	IAVI; KAVI	February 2003	UK; Kenya	DNA.HIVA MVA.HIVA	gag + 25 CTL epitopes gag + 25 CTL epitopes	A A	HIV-DNA +/-MVA boost
HVTN 026 (HVTN)	NIAID; Aventis/ VaxGen	June 2000	Brazil, Haiti, Peru, Trinidad and Tobago	ALVAC vCP1452 MN rgp120	env, gag and pol + CTL epitopes; rgp120	B	Canarypox virus vector +/-rgp120 boost
Phase I/II (Mid-sized trials in low-risk populations; test vaccine safety, immunogenicity)							
N/A	UNSW; AVC	June 2003	Australia	pHIS-HIV-B rFPV-HIV-B	gag, RT, rev, tat, vpu, env gag, RT, rev, tat, vpu, env	B B	DNA Vaccine + fowlpox boost
IAVI 006	IAVI/MRC; Cobra/IDT	April 2002	UK (2)	DNA.HIVA MVA.HIVA	gag + 25 CTL epitopes gag + 25 CTL epitopes	A A	HIV-DNA +/-MVA boost
Phase I (Small trials in low-risk populations; test vaccine safety, immunogenicity)							
HVTN 050/ Merck 018	NIAID; Merck	September 2004	Malawi, South Africa	MRKAd5 HIV-1	gag	B	Replication defective Ad-5 vector
ANRS VAC 16	ANRS; Biovector SA	July 2004	France (6)	LIPO-4T (LPHIV-1)	4 lipopeptides containing CTL epitopes (from Gag, Pol-RT, Pol, Nef)	B	Safety and immunogenicity of lipopeptides LIPO-4T, by two administration routes.
VRC 006	NIAID; GenVec	May 2004	US	VRC-HIVADV014-00-VP	gag/pol polyprotein env	B A,B,C	Safety, tolerability, immune response of a multiclade HIV adenoviral vector vaccine in uninfected adults.
N/A	AVANT; NIAID; WRAIR	May 2004	US	LFn-p24	Anthrax-derived polypeptide LFn gag p24 protein	B	18 health volunteers. Aim: inducing strong and persistent HIV-1 gag specific CD8 T Cell responses.
N/A	UMMS; ABL	April 2004	US	DNA Proteins	gag + 5 env 5 recombinant gp120	A,B,C,E A,B,C,E	DNA prime: 1 gag gene (C) + 5 env genes (A, 2 B, C, E). Boost: 5 gp120 (same isolates as DNA). Adjuvant: QS21.
HVTN 049	NIAID; Chiron	December 2003	US (11)	gag and env DNA oligomeric (-V2) gp140	gag, env gp140	B B	DNA primer + cationic polylactide coglycolide (PLG) microparticles; booster + MF59 adjuvant
IAVI A001	IAVI; Targeted Genetics	December 2003	Belgium (2); Germany (2)	tgAAC09 AAV	gag, protease, rt	C	Recombinant AAV vector; single shot
IAVI C001	IAVI; ADARC; Vical	December 2003	US (2)	ADVAX DNA	gag, env, pol, nef, tat	C	Multi-gene approach
N/A	ISS; Parexel	December 2003	Italy (3)	tat DNA	tat	B	
IAVI 011	IAVI, SAAVI IDT	November 2003	South Africa (2), UK (1), Switzerland (1)	MVA-HIVA	gag + 25 CTL epitopes	A	Dose response
EnvPro	St Jude's	September 2003	US	EnvPro protein	gp140	D	Purified env protein
N/A	Merck; Aventis Pasteur	2003	US (17)	MRKAd5 HIV-1; ALVAC vCP205	gag env, gag, pol	B	MRKAd5 HIV-1 prime, ALVAC vCP205 boost
HVTN 040	NIAID, SAAVI; AlphaVax	July 2003	US (4); South Africa (2)	AVX101 VEE	gag	C	Safety and immunogenicity of VEE vector
EV01	Imperial College; EuroVac; Aventis	July 2003	UK; Switzerland	NYVAC-HIV C	gag, pol, nef, env	C	Safety and immunogenicity of NYVAC

ABL: Advanced BioScience Laboratories, Inc.; **ADARC:** Aaron Diamond AIDS Research Center; **AFRIMS:** Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand, is a joint U.S.-Royal Thai Army Command; **AlphaVax:** AlphaVax Human Vaccines Inc.; **ANRS:** Agence Nationale de Recherche sur le SIDA; **AVANT:** AVANT Immunotherapeutics, Inc.; **AVC:** Australian Vaccine Consortium; **Aventis:** Aventis Pasteur; CAN: Canada; **Chiron:** Chiron Corporation; **CTL:** cytotoxic T-lymphocyte; **GSK:** GlaxoSmithKline; **HVTN:** HIV Vaccine Trials Network; **IAVI:** International AIDS Vaccine Initiative; **IDT:** Impfstoffwerk Dessau Tornau GmbH; **ISS:** Istituto Superiore di Sanità; **KAVI:** Kenyan AIDS Vaccine Initiative; **MoH:** Ministry of Health (Thailand); **MRC:** UK Medical Research Council; **NIAID:** U.S. National Institute Allergy and Infectious Diseases; **NL:** Netherlands; **PACTG:** Pediatric AIDS Clinical Trials Group; **PR:** Puerto Rico; **SAAVI:** South African AIDS Vaccine Initiative; **St Jude's:** St Jude's Childrens Hospital; **TT:** Tetanus Toxoid; **UMMS:** University of Massachusetts Medical School; **UNSW:** University of New South Wales; **US:** United States; **UVRI:** Uganda Virus Research Institute; **VEE:** Venezuelan equine encephalitis; **VRC:** Vaccine Research Center; **WRAIR:** Walter Reed Army Institute of Research

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Phase I (Small trials in low-risk populations; test vaccine safety, immunogenicity) (continued)							
ANRS VAC 14	ANRS; Aventis	June 2003	France (2)	gp160MN/LAI-2	gp120 (MN strain), gp41 (LAI strain)	B	Safety and immunogenicity, using several routes
HVTN 048	NIAID; Epimmune	April 2003	US (2); Botswana	EP HIV-1090 DNA	21 CTL epitopes from gag, pol, env, nef, rev, vpr	B	Safety and immunogenicity
IAVI 009	IAVI/UVRI; Cobra/IDT	January 2003	Uganda	DNA.HIVA MVA.HIVA	gag + 25 CTL epitopes gag + 25 CTL epitopes	A A	HIV-DNA +/-MVA boost
IAVI 008	IAVI/KAVI; IDT	January 2003	Kenya	MVA.HIVA	gag + 25 CTL epitopes	A	MVA boost of volunteers vaccinated with DNA (IAVI 002)
HVTN 045	NIAID; Vical	January 2003	US (3)	pGA2/JS2 DNA	gag, rt, env, tat, rev, vpu	B	Safety, immunogenicity, dose response
03-I-0022	NIAID/VRC; Vical	November 2002	US	VRC-HIVDNA009-00-VP	gag, pol, nef (clade B); env (clades A, B, C)	A, B, C	Safety and immunogenicity of a multiclade vaccine
N/A	FIT Biotech	July 2002	Finland	GTU-Nef DNA	nef	B	
B011; RV 138	WRAIR; Aventis	July 2002	US	ALVAC-HIV vCP205	env, gag, pol	B	Response to vaccine subcutaneously (via dendritic cells), intradermally, or intramuscularly
HVTN 041	NIAID; GSK	February 2002	US (10)	NefTat gp120w61d	nef, tat gp120	B	NefTat fusion protein +/- gp120 in adjuvant AS202A
HVTN 039	NIAID; Aventis	December 2001	US	ALVAC vCP1452	env, gag, pol + CTL epitopes	B	Safety, immunogenicity, dose response
IAVI 005	IAVI/MRC; IDT	October 2001	UK	MVA-HIVA	gag + 25 CTL epitopes	A	MVA boost of volunteers vaccinated with DNA (IAVI 001)
01-I-0079	NIAID/VRC; Vical	January 2001	US	VRC4302 DNA	gag, pol	B	Dose and immune response
N/A	Merck	2001	US	gag DNA Ad5 gag	gag gag	B B	Evaluation of DNA vs. Ad5 prime + Ad5 boost
N/A	Merck	2002	US	gag DNA	gag	B	Dose response
N/A	Merck	2000	US	Ad5 gag	gag	B	Dose response

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