THE LANCET Infectious Diseases

Supplementary webappendix

This webappendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Gray GE, Moodie Z, Metch B, et al, on behalf of the HVTN 503/ Phambili study team. Recombinant adenovirus type 5 HIV gag/pol/nef vaccine in South Africa: unblinded, long-term follow-up of the phase 2b HVTN 503/Phambili study. *Lancet Infect Dis* 2014; published online Feb 20. http://dx.doi.org/10.1016/S1473-3099(14)70020-9.

Supplemental Table 1: Description of the MITT cohort baseline characteristics stratified by gender

	Men (N=441)		Women (N=359)		
	Vaccine (N=222)	Placebo (N=219)	Vaccine (N=178)	Placebo (N=181)	Total (N=800)
Baseline Adenovirus 5 status					
Seronegative	50 (22.5%)	48 (21.9%)	25 (14.0%)	31 (17.0%)	154 (19.2%)
Seropositive	172 (77.5%)	171 (78.1%)	153 (86.0%)	150 (82.9%)	646 (80.8%)
Age (years)					
Median (range)	22 (18,35)	22 (18,35)	23 (18, 35)	23 (18,34)	22 (18,35)
Race					
Black	222 (100.0%)	215 (98.2%)	176 (98.9%)	179 (98.9%)	792 (99.0%)
Other	0 (0.0%)	4 (1.8%)	2 (1.1%)	2 (1.1%)	8 (1.0%)
HSV-2 status					
Positive	40 (18.0%)	32 (14.7%)	90 (50.8%)	86 (47.5%)	248 (31.1%)
Negative	177 (79.7%)	181 (83.0%)	84 (47.5%)	93 (51.4%)	535 (67.0%)
Atypical	5 (2.3%)	5 (2.3%)	3 (1.7%)	2 (1.1%)	15 (1.9%)
Circumcised (men only)					
At enrolment	61 (27.5%)	68 (31.1%)			129 (29.3%)
During the study	72 (32.4%)	67 (30.6%)			139 (31.5%)
Uncircumcised throughout	85 (38.3%)	80 (36.5%)			165 (37.4%)
No on study assessment*	4 (1.8%)	4 (1.8%)			8 (1.8%)
Risk behaviors (previous 6 months)					
Number of sexual partners					
Median (range)	2 (1, 20)	2 (1, 14)	1 (1,3)	1 (1,3)	1 (1,20)
Unprotected vaginal sex	129 (58.1%)	125 (57.1%)	103 (57.9%)	96 (53.0%)	453 (56.6%)
Unprotected anal sex	4 (1.8%)	8 (3.7%)	4 (2.2%)	5 (2.8%)	21 (2.6%)
Drinking/drugs with sex	93 (41.9%)	81 (37.0%)	26 (14.6%)	14 (7.7%)	214 (26.8%)
Had a main partner	155 (69.8%)	149 (68.0%)	151 (84.8%)	150 (82.9%)	605 (75.6%)
Had a main partner but apart regularly	97 (43.7%)	95 (43.4%)	83 (46.6%)	73 (40.3%)	348 (43.5%)
Had a casual or anonymous partner	109 (49.1%)	100 (45.7%)	22 (12.4%)	18 (9.9%)	249 (31.1%)
Away from home regularly (men only)	46 (20.7%)	48 (21.9%)			94 (21.3%)
Heavy drinking	49 (22.1%)	59 (26.9%)	7 (3.9%)	9 (5.0%)	124 (15.5%)
Smoked dagga (marijuana)	77 (34.7%)	80 (36.5%)	8 (4.5%)	5 (2.8%)	170 (21.3%)

Behavioral risk data were based on self-reported behavior within 6 months prior to screening. Apart regularly from main partner was defined as living in a different location or partner regularly away from home for 3 or more days per week or for men, being away from home for 3 or more days per week. Heavy drinking was defined as having >5 drinks per day on at least 10 days within the six month reporting period. *Men with no on study assessment have missing data for circumcision as status was determined by physical exam.

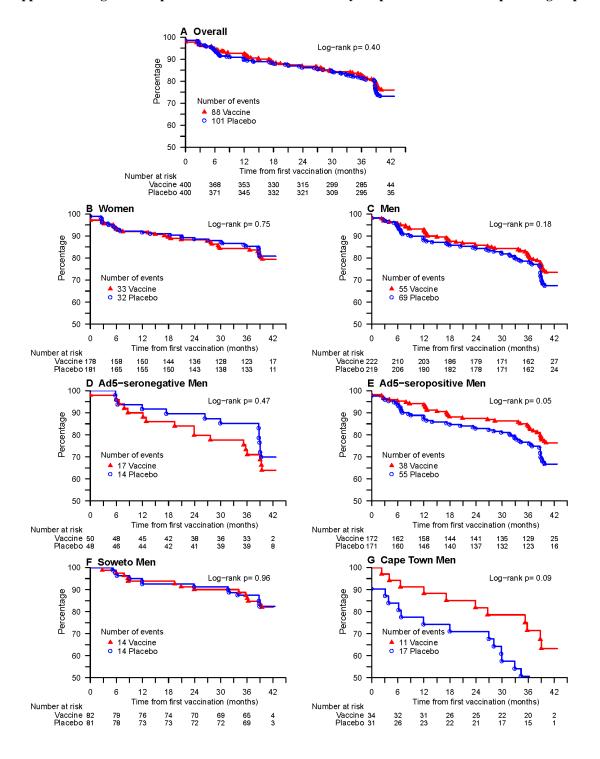
Supplemental Table 2: Men circumcised on study by site and treatment

Site	Total # (# infected)	Vaccine # (# infected)	Placebo # (# infected)
All	139 (5)	72 (3)	67 (2)
Soweto	67 (1)	33 (1)	34 (0)
Cape Town	6 (0)	5 (0)	1 (0)
KOSH	43 (1)	22 (0)	21 (1)
eThekwini	22 (1)	11 (2)	11 (1)
MEDUNSA	1(0)	1(0)	0 (0)

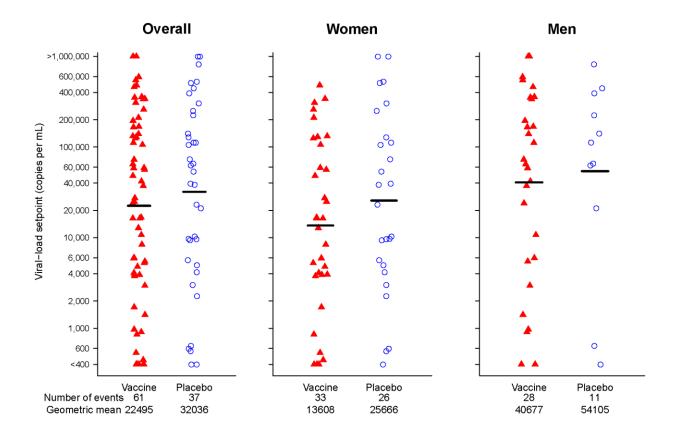
Supplemental Table 3. Annualized dropout rates by treatment arm

	MITT Cohort		Vaccine		Placebo	
Cohort	# Dropout (# enrolled)	Annualized Dropout Rate	# Dropout (# enrolled)	Annualized Dropout Rate	# Dropout (# enrolled)	Annualized Dropout Rate
Overall	189 (800)	8.3%	88 (400)	7.7%	101 (400)	8.8%
Men	124 (441)	9.7%	55 (222)	8.5%	69 (219)	10.9%
Women	65 (359)	6.4%	33 (178)	6.7%	32 (181)	6.2%
Soweto	43 (308)	4.6%	23 (154)	5.1%	20 (154)	4.1%
Cape Town	50 (165)	11.4%	21 (84)	9.3%	29 (81)	13.7%
KOSH	74 (221)	12.2%	36 (110)	11.8%	38 (111)	12.7%
eThekwini	6 (53)	4.0%	2 (26)	2.7%	4 (27)	5.2%
MEDUNSA	16 (53)	10.3%	6 (26)	7.9%	10 (27)	12.7%

Supplemental Figure 1. Kaplan-Meier curves of time to study dropout for vaccine and placebo groups



Supplemental Figure 2. Plasma viral load set-point by treatment group



Viral load set-point is the geometric mean of the viral loads obtained at about 2 and 3 after detection of infection. The bar denotes the geometric mean titers of the plasma viral load. Two woman in the vaccine group were excluded from the analysis: one because of a 6 month delay in confirming HIV infection and the other had no post diagnosis viral load measurements.

Supplemental Figure 3. Cumulative HIV-1 incidence curves by number of vaccinations received prior to HIV-1 infection

