

Supplementary material

Table S1. Baseline demographic and clinical factors between rotavirus shedders and non-shedders, as determined by ELISA, stratified by vaccination status: three injections of P2-VP8-P[8] vaccine (30µg and 60µg doses; n=91) or placebo (n=44)

	30µg and 60µg P2-VP8-P[8] recipients			Placebo recipients		
	Not shedding ^a (N=76)	Shedding ^b (N=15)	P-value	Not shedding ^a (N=27)	Shedding ^b (N=17)	P-value
Clinical and demographic factors						
Male sex, n (%)	36 (47.4)	8 (53.3)	0.673	12 (44.4)	7 (41.2)	0.831
Age in days, median (range)	45 (42-55)	45 (42-54)	0.360	44 (42-53)	44 (42-49)	0.751
HIV-exposed, n (%)	10 (13.2)	4 (26.7)	0.237 ^c	4 (14.8)	2 (11.8)	1.000 ^c

ELISA: Enzyme-linked immunoassay; HIV: human immunodeficiency virus

^a ELISA negative, ^b ELISA positive ^c Fisher's exact test

VISIT WINDOW	PROCEDURES	AGE (RANGE)
Day -7 to -1	Screening Immunogenicity blood draw Safety blood draw	5 – 7 weeks
Day 0	Injection 1 P2-VP8/placebo*	6 – 8 weeks
Day 3 and 7 (± 1)	Safety visits Safety blood draw (Day 7)	
Day 28 (-2, +7)	Injection 2 P2-VP8/placebo#	10 – 13 weeks
Day 31 and 35 (± 1)	Safety visits	
Day 56 (-2, +7)	Injection 3 P2-VP8/placebo^	14 – 17 weeks
Day 59 and 63 (± 1)	Safety visits	
Day 84 (± 4)	Rotarix dose 1 Immunogenicity blood draw	18 – 22 weeks+
Day 89, 91, 93	Stool collection for Rotarix shedding	18 – 23 weeks
Day 112 (± 14)	Rotarix dose 2	22 – 27 weeks
Day 140 (± 14)	Rotarix dose 3	26 – 32 weeks
Day 224 (± 14)	Final visit Immunogenicity blood draw	9 months (36 – 40 weeks)

Figure S1: Schedule of events for infants.

Note: From Groome, M. J.; Koen, A.; Fix, A.; Page, N.; Jose, L.; Madhi, S. A.; McNeal, M.; Dally, L.; Cho, I.; Power, M.; Flores, J.; Cryz, S., Safety and immunogenicity of a parenteral P2-VP8-P[8] subunit rotavirus vaccine in toddlers and infants in South Africa: a randomised, double-blind, placebo-controlled trial. *Lancet Infect Dis* 2017, 17, (8), 843-853 (Supplementary Material) [12]. CC-BY-NC.

* Given concomitantly with OPV, Heberbiovac-HB[®], Prevenar13[®] and Pentaxim[®]

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+ Median age on day 84 is 19 weeks in all treatment groups