

Table A: Power calculations for sample size and allocation ratio

Comparison	Mean (SD) log MenC rSBA used	Significance	Non-inferiority margin	Estimated difference	Power	Single Infant Dose MenC-CRM group	Two Infant Dose MenC-CRM group	Single Infant Dose MenC-TT group	Control (0 dose) group	TOTAL REQUIRED
Primary	3.5 (0.9) [a]	2.5% (1-sided)	10%	-0.35	0.9	140	140			
Secondary	3.32 (0.72) [a]	5% (2-sided)		0.332	0.9	140		100		
Secondary (not reported in current paper)	2.85 (0.48) [b]	5% (2-sided)		10%	0.95	60			56	
	Adjusting for 12.5% dropout/sample loss					160	160	114	64	498
	Allocation Ratio					10	10	7	4	

[a] Borrow R, Goldblatt D, Finn A, et al. Infect Immun. Oct 2003;71(10):5549-5555.

[b] Snape MD, MacLennan J, Lockhart S, et al. Paed Infect Dis J. 2009. Feb;28(2):92-7.

Table B: MenC rSBA GMTs induced at the specified timelines following the different MenC vaccination schedules

Blood sampling Visit	Single infant dose MenC-CRM (Group 1)		Two infant dose MenC-CRM (Group 2)		Control Group (Group 3)		Single infant dose MenC-TT (Group 4)	
	N	GMTs (95% CI)	N	GMTs (95% CI)	N	GMTs (95% CI)	N	GMTs (95% CI)
5 month	144	53.56 (42.95-66.83)	137	620.54 (494.31-778.04)	56	2.18* (1.83-2.59)	99	169.27 (129.72 – 221.31)
12 month	147	4.42 (3.32 – 5.87)	128	8.31 (6.11-11.30)	54	2.0 (2.0 – 2.0)	93	9.29 (6.47 – 13.3)
13 month	136	660.61 (498.04 – 876.24)	126	295.36 (220.30-398.11)	54	121.59 (77.8-190.11)	84	2779.24 (1940.89 – 3981.07)
24 month	136	6.17 (4.56 – 8.35)	127	4.09 (2.99-5.58)	55	5.02 (3.13 – 8.05)	95	123.41 (86.1 – 177.01)

*One infant in the Control Group had detectable MenC rSBA, very likely reflecting transplacentally acquired maternal antibody.

Table C: Frequency of expected local and systemic adverse events by group (ITT population)

Adverse events	Single infant dose MenC-CRM (Group 1)		Two infant dose MenC-CRM (Group 2)		Control Group (Group 3)		Single infant dose MenC-TT (Group 4)	
	n	%	n	%	n	%	n	%
*2 months: Systemic								
Fever \geq 38°C	3	2	3	2	1	2	4	3
Decreased appetite	52	32	54	34	17	26	36	31
Drowsiness	99	60	92	58	35	53	70	60
Irritability	102	62	115	72	43	65	78	67
*3 months: Local								
Pain	24	15	35	22			18	16
Redness	57	35	66	45			42	38
Swelling	19	12	24	16			16	14
Induration	31	19	39	25			23	20
*3 months: Systemic								
Fever \geq 38°C	4	2	5	3	3	5	2	2
Decreased appetite	42	25	33	21	11	17	29	25
Drowsiness	74	45	80	50	28	43	45	39
Irritability	102	62	105	66	37	57	73	63
4 months: Local								
Pain			27	17				
Redness			73	49				
Swelling			25	16				
Induration			40	26				
*4 months: Systemic								
Fever \geq 38°C	5	3	7	4	2	3	3	3
Decreased appetite	34	21	41	26	10	16	27	24
Drowsiness	65	39	65	41	23	37	47	42
Irritability	95	58	92	59	38	60	71	63
*5 months: Local								
Pain	35	22	38	25	12	19	30	29
Redness	74	49	76	56	28	47	48	50
Swelling	31	20	34	23	13	22	23	23
Induration	44	29	42	28	16	26	31	31
*5 months: Systemic								
Fever \geq 38°C	12	8	15	10	6	10	4	4
Decreased appetite	50	32	52	35	18	29	33	32
Drowsiness	62	39	51	34	21	34	37	35
Irritability	85	53	86	57	38	61	58	55

*All p values for all comparisons between the groups were >0.05.