APPENDIX 1: SCHEDULE OF VISITS AND PROCEDURES

Trial A schedule

Visit number	1	2 and 3	4	5[9]	5.2	6	7	8	9	10	11
Weeks from 1st immunisation	Screen -8[1]	-6[10], -4, -2 Rx only	0 IMM	4 IMM	4 weeks +45 days	8 PE [IMM]	20 Rx only	28 IMM	32 PE/SE[2]	44 Rx only	52 SE [IMM]
Randomised intensive vs standard praziquantel intervention											
PZQ intensive arm (x)		x				x[3]	x		x[3]	x	x[3]
PZQ standard arm						x[3]					x[3]
Albendazole						x[3]			x[3]		x[3]
Vaccines											
BCG			x								
YF-17D				x							
Ty21a				x							
HPV				x		[x][4]		x			
Td								x			[x][5]
Investigations/procedures											
Inclusion/exclusion criteria	x										
Informed consent	x										
Questionnaire	x		x	x	x	x		x	x		x
Examination	x		(x)	(x)	(x)	(x)		(x)	(x)		(x)
Urine β-HCG test (female only) 1mL	x		x	x				x			
Urine YF viral load					x						
Stool for PCR and storage	x							x			x
Stool for coproantibody and storage	x					x					
Lactulose/mannitol test[6]						x					
Blood samples											
Malaria PCR			x	x				x			x
Serology for HIV, prior malaria and *S. mansoni*	x										
Mansonella perstans	x										
Serum/plasma CAA	x		x	x		x		x	x		x
Hb[8] / Full blood count	x		x	x				x			
Assessments of pre-immunisation responses, and/or vaccine response outcomes and/or exploratory immunology; storage[7]	*		x	x		x		x	x		x
Blood for gene expression			x	x				x			
Blood vol (mL)	~~1~~4		2~~7~~1	1~~7~~6		10		2~~7~~1	10		1~~4~~0
Cumulative blood vol (mL)[7]	~~1~~4		3~~1~~5	~~485~~1		~~586~~1		8~~5~~2	9~~5~~2		10~~9~~2

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IMM immunisations, PE primary endpoint, SE secondary endpoint, Rx only treatment only
Immunisation days highlighted in orange, primary end point days in red, days for treatment only in grey
(x) performed if clinically indicated

1. Screening and enrolment into Project A will take place about 8 weeks before immunisation 0 to allow initiation of the praziquantel intervention.
2. Week 32 is primary endpoint for responses to Td given at 28 weeks; secondary endpoint for HPV booster
3. Treatments given after sampling when schedules coincide
4. Week 8 HPV dose will be given for previously-unvaccinated girls aged ≥14 years
5. Week 52 Td booster dose will be provided as a service
6. Lactulose/mannitol test of intestinal permeability to be performed in sub-groups of ~100 participants from each arm of Project A
7. Exploratory immunology blood volume will be guided by guidelines from Harvard Mass General, where a maximum of 3ml/kg body weight is taken at any one time point and not more than 3ml/kg is taken over any 8-week period (ref http://www.drgreene.com/21_1616.html.) These guidelines have been followed in a previous study vaccinating adolescents with investigational tuberculosis vaccine MVA85A (in Uganda).[73] The total blood volume planned is 5861 ml over the initial intensive sampling period of 8 weeks. Revision of sample volumes based on weight will only be required for participants who weigh less than 1921 kg; the average weight of children aged 9 years is expected to be 28kg (with 21kg the 3rd centile) with greater weights for older children.[74]
8. At baseline, it will only be Hb estimation by Haemocue
9. Oral typhoid vaccine doses will be administered on four alternate days namely visit 5, 5.1, 5.2 and 5.3.
10. The first PZQ treatment at week -6 will be administered at the end of the screening visit

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