

# THE LANCET

## Supplementary appendix

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**Appendix 1. Specific antibody responses to RBD, neutralizing antibodies to live SARS-CoV-2 and pseudovirus at baseline**

	<b>Vaccine at <math>1 \times 10^{11}</math> vp (n=253)</b>	<b>Vaccine at <math>5 \times 10^{10}</math> vp (n=129)</b>	<b>Placebo (n=126)</b>
<b>Baseline</b>			
<b>ELISA antibodies to RBD</b>			
$\geq$ detection limit (1:40).	11 (4%)	6 (5%)	2 (2%)
GMT	21.5 (20.6-22.5)	21.9 (20.4-23.6)	20.7 (19.7-21.8)
<b>Neutralizing antibodies to live SARS-CoV-2</b>			
$\geq$ detection limit (1:8).	0	0	1 (1%)
GMT	4.0 (-)	4.0 (-)	4.1 (3.9-4.3)
<b>Neutralization antibodies to pseudovirus</b>			
$\geq$ detection limit (1:10).	9 (4%)	8 (6%)	1 (1%)
GMT	5.2 (5.1-5.3)	5.5 (5.1-6.0)	5.1 (4.9-5.4)

Data are mean (95% CI) or n (%). GMT = geometric mean antibody titre. RBD = receptor binding domain. vp=viral particles

**Appendix 2. Specific antibody responses to RBD, neutralizing antibodies to live SARS-CoV-2 and pseudovirus post-vaccination according to pre-existing Ad5.**

	Vaccine at $1 \times 10^{11}$ vp (n=253)	Vaccine at $5 \times 10^{10}$ vp (n=129)	Placebo (n=126)
<b>At day 14</b>			
<b>ELISA antibodies to RBD</b>			
Pre-existing Ad5 $\leq$ 200	n=127	n=54	n=61
GMT	194.1 (157.0-240.0)	173.0 (122.5-244.2)	21.0 (19.1-23.0)
Seroconversion	96, 76%	40, 76%	0
Pre-existing Ad5 $>$ 200	n=126	n=75	n=65
GMT	45.7 (39.0-53.7)	51.6 (37.5-70.9)	20.3 (19.7-21.0)
Seroconversion	38, 30%	25, 33%	0
<b>At day 28</b>			
<b>ELISA antibodies to RBD</b>			
Pre-existing Ad5 $\leq$ 200	n=127	n=54	n=61
GMT	995.2 (853.8-1160.1)	826.7 (638.3-1070.7)	21.2 (19.4-23.2)
Seroconversion	125, 98%	54, 100%	0
Pre-existing Ad5 $>$ 200	n=126	n=75	n=65
GMT	431.6 (356.5-522.5)	437.5 (331.3-577.7)	20.3 (19.7-21.0)
Seroconversion	119, 94%	71, 95%	0
<b>Neutralizing antibodies to live SARS-CoV-2</b>			
Pre-existing Ad5 $\leq$ 200	n=127	n=54	n=61
GMT	31.1 (25.5-37.9)	27.0 (18.9-38.5)	4.1 (3.9-4.4)
Seroconversion	94, 74%	34, 63%	0
Pre-existing Ad5 $>$ 200	n=126	n=75	n=65
GMT	12.2 (10.1-14.8)	13.8 (10.1-19.0)	4.1 (3.9-4.3)
Seroconversion	54, 43%	27, 36%	1, 2%
<b>Neutralization antibodies to pseudovirus</b>			
Pre-existing Ad5 $\leq$ 200	n=127	n=54	n=61
GMT	85.7 (70.0-104.9)	70.4 (55.2-90.0)	5.9 (5.0-7.0)
Seroconversion	117, 92%	49, 91%	1, 2%
Pre-existing Ad5 $>$ 200	n=126	n=75	n=65
GMT	43.8 (36.0-53.4)	46.5 (34.7-62.4)	5.2 (5.0-5.4)
Seroconversion	97, 77%	58, 77%	0

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Data are mean (95% CI) or n (%). GMT = geometric mean antibody titre. RBD = receptor binding domain. Seroconversion was defined as at least a four-fold increase in post-vaccination titre from baseline. All the comparisons across the three treatment groups in terms of the above measurements show significant difference, with p values less than 0.0001, respectively. Multiple comparisons showed no significant difference between the dose group of  $1 \times 10^{11}$  vp and  $5 \times 10^{10}$  vp. vp=viral particles

**Appendix 3. Logistic regression analysis of seroconversion rate of S-protein by ELISA-RBD at day 28 post-vaccination with the baseline characters, vaccine dose and pre-existing Ad5 antibodies.**

Model parameter	Estimates	P value	OR	
			Point estimates	95%CI by Wald
Intercept	8.49	<0.0001		
Dose group of $1 \times 10^{11}$ vp*	-0.13	0.83	0.88	0.25-3.04
Age	-0.08	0.0018	0.92	0.87-0.97
Sex(male)	-0.26	0.66	0.8	0.24-2.46
Pre-existing Ad5 antibodies (>200)	-1.53	0.052	0.2	0.05-1.02

\* The independent variables are the dose group (the dose group of  $5 \times 10^{10}$  vp as the reference), age (continuous variable), sex (female as reference), and the level of Ad5 antibodies pre-vaccination ( $\leq 200$  as reference) included in a multivariable analysis. vp=viral particles

**Appendix 4. Logistic regression analysis of seroconversion rate of neutralizing antibodies to live SARS-CoV-2 at day 28 post-vaccination with the baseline characters, vaccine dose and pre-existing Ad5 antibodies.**

Model parameter	Estimates	P value	OR	
			Point estimates	95%CI by Wald
Intercept	2.51	<0.0001		
Dose group of $1 \times 10^{11}$ vp*	0.43	0.068	1.54	0.97-2.44
Placebo group*	-5.14	<0.0001	0.006	0.001-0.04
Age	-0.04	<0.0001	1.0	0.94-0.98
Sex(male)	-0.39	0.085	0.7	0.44-1.06
Pre-existing Ad5 antibodies (>200)	-1.24	<0.0001	0.3	0.19-0.45

\* The independent variables are the dose group (the dose group of  $5 \times 10^{10}$  vp as the reference), age (continuous variable), sex (female as reference), and the level of Ad5 antibodies pre-vaccination ( $\leq 200$  as reference) included in a multivariable analysis. vp=viral particles

**Appendix 5. Logistic regression analysis of seroconversion rate of neutralizing antibodies to pseudovirus at day 28 post-vaccination with the baseline characters, vaccine dose and pre-existing Ad5 antibodies.**

Model parameter	Estimates	P value	OR	
			Point estimates	95%CI by Wald
Intercept	3.17	<0.0001		
Dose group of $1 \times 10^{11}$ vp *	0.07	0.83	1.07	0.59-1.92
Placebo group*	-6.84	<0.0001	0.001	0.00-0.01
Age	-0.02	0.046	0.98	0.96-1.00
Sex(male)	0.23	0.43	1.25	0.71-2.20
Pre-existing Ad5 antibodies (>200)	-1.16	0.0003	0.32	0.17-0.59

\* The independent variables are the dose group (the dose group of  $5 \times 10^{10}$  vp as the reference), age (continuous variable), sex (female as reference), and the level of Ad5 antibodies pre-vaccination ( $\leq 200$  as reference) included in a multivariable analysis. vp=viral particles



**Appendix 6. Specific antibody responses to RBD, neutralizing antibodies to live SARS-CoV-2 and pseudovirus post-vaccination stratified according to age.**

	<b>Vaccine at 1×10<sup>11</sup> vp (n=253)</b>	<b>Vaccine at 5×10<sup>10</sup> vp (n=129)</b>	<b>Placebo (n=126)</b>	<b>p value</b>
<b>At day 14</b>				
<b>ELISA antibodies to RBD</b>				
18-44 years old	n=152	n=80	n=77	
GMT	126.9 (102.9-156.5)	106.0 (77.2-145.5)	20.3 (19.7-20.8)	<0.0001
Seroconversion	97, 64%	48, 61%	0	<0.0001
45-54 years old	n=67	n=32	n=35	
GMT	67.2 (50.9-88.9)	64.8 (37.5-111.9)	20.0	<0.0001
Seroconversion	27, 40%	12, 38%	0	<0.0001
≥55 years old	n=34	n=17	n=14	
GMT	49.4 (33.9-72.0)	51.4 (25.5-103.6)	24.5 (15.8-38.2)	0.11
Seroconversion	10, 29%	5, 29%	0	0.045
<b>At day 28</b>				
<b>ELISA antibodies to RBD</b>				
18-44 years old	n=152	n=80	n=77	
GMT	791.8 (678.1-924.6)	700.0 (553.0-886.2)	20.3 (19.7-20.8)	<0.0001
Seroconversion	149, 98%	79, 99%	0	<0.0001
45-54 years old	n=67	n=32	n=35	
GMT	488.4 (365.3-652.9)	424.2 (272.6-660.2)	20.0*	<0.0001
Seroconversion	63, 94%	31, 97%	0	<0.0001
≥55 years old	n=34	n=17	n=14	
GMT	509.0 (349.0-742.2)	383.1 (203.9-719.6)	25.7 (17.0-38.7)	<0.0001
Seroconversion	32, 94%	15, 88%	0	<0.0001
<b>Neutralizing antibodies to live SARS-CoV-2</b>				
18-44 years old	n=152	n=80	n=77	
GMT	24.6 (20.2-29.9)	21.2 (15.5-29.0)	4.1 (3.9-4.3)	<0.0001
Seroconversion	104, 68%	42, 53%	1, 1%	<0.0001
45-54 years old	n=67	n=32	n=35	
GMT	16.6 (12.7-21.8)	17.8 (10.5-30.3)	4.0	<0.0001
Seroconversion	35, 52%	14, 44%	0	<0.0001
≥55 years old	n=34	n=17	n=14	

	Vaccine at $1 \times 10^{11}$ vp (n=253)	Vaccine at $5 \times 10^{10}$ vp (n=129)	Placebo (n=126)	p value
GMT	9.6 (6.9-13.5)	9.5 (6.0-15.0)	4.6 (3.4-6.4)	0.028
Seroconversion	9, 26%	5, 29%	0	0.055
<b>Neutralization antibodies to pseudovirus</b>				
18-44 years old	n=152	n=80	n=77	
GMT	72.4 (60.0-87.3)	58.2 (45.8-74.0)	5.5 (4.9-6.1)	<0.0001
Seroconversion	134, 88%	68, 85%	1, 1%	<0.0001
45-54 years old	n=67	n=32	n=35	
GMT	48.6 (36.6-64.4)	56.1 (34.7-90.5)	5.1 (4.9-5.4)	<0.0001
Seroconversion	52, 78%	26, 81%	0	<0.0001
$\geq 55$ years old	n=34	n=17	n=14	
GMT	46.6 (30.6-71.0)	42.4 (23.9-75.3)	6.8 (4.0-11.7)	<0.0001
Seroconversion	28, 82%	13, 76%	0	<0.0001

Data are mean (95% CI) or n (%). GMT = geometric mean antibody titre. RBD = receptor binding domain. Seroconversion was defined as at least a four-fold increase in post-vaccination titre from baseline. P value was generated by comparisons across the three treatment groups. Pairwise comparisons showed no significant difference between the dose group of  $1 \times 10^{11}$  vp and  $5 \times 10^{10}$  vp. vp=viral particles

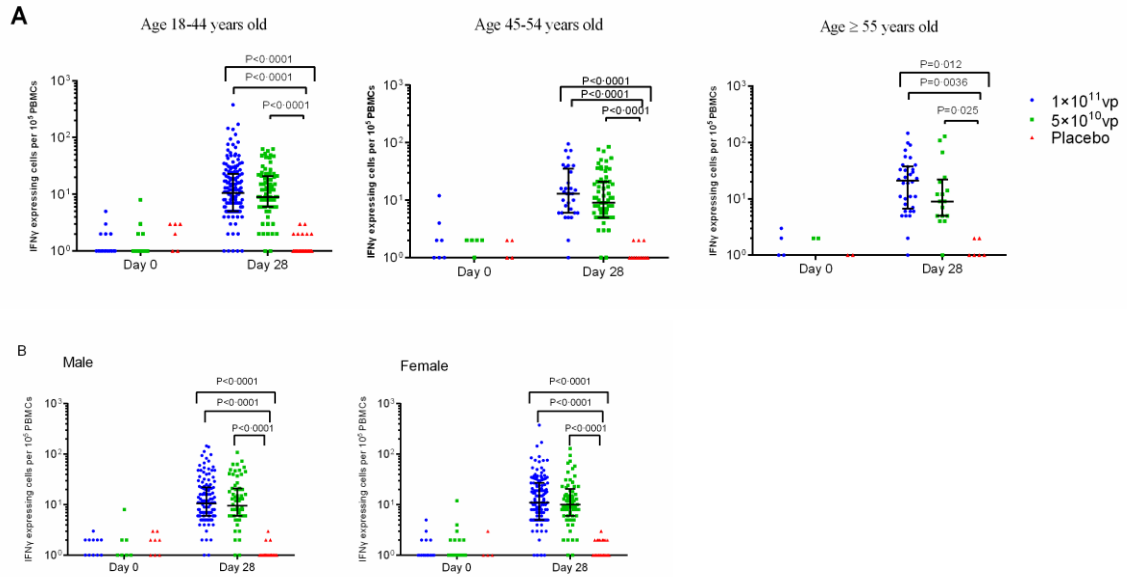
**Appendix 7. Specific antibody responses to RBD, neutralizing antibodies to live SARS-CoV-2 and pseudovirus post-vaccination stratified according to sex.**

	Vaccine at $1 \times 10^{11}$ vp (n=253)	Vaccine at $5 \times 10^{10}$ vp (n=129)	Placebo (n=126)
<b>At day 14</b>			
<b>ELISA antibodies to RBD</b>			
Male	n=126	n=64	n=64
GMT*	104.2 (83.0-130.8)	65.8 (48.5-89.2)	20.0 -
Seroconversion	69, 55%	31, 49%	0
Female	n=127	n=65	n=62
GMT	85.7 (68.3-107.4)	109.3 (73.1-163.4)	21.3 (19.3-23.5)
Seroconversion	65, 51%	34, 52%	0
<b>At day 28</b>			
<b>ELISA antibodies to RBD</b>			
Male	n=126	n=64	n=64
GMT	676.5 (563.0-812.7)	496.7 (390.1-632.4)	20.0 -
Seroconversion	120, 95%	63, 98%	0
Female	n=127	n=65	n=62
GMT	637.3 (525.8-772.5)	655.0 (475.5-902.3)	21.5 (19.6-23.6)
Seroconversion	124, 98%	62, 95%	0
<b>Neutralizing antibodies to live SARS-CoV-2</b>			
Male	n=126	n=64	n=64
GMT‡	20.7 (16.6-25.7)	13.1 (9.8-17.5)	4.0 -
Seroconversion§	75, 60%	24, 38%	0
Female	n=127	n=65	n=62
GMT	18.5 (15.0-22.8)	25.4 (17.5-36.9)	4.2 (3.9-4.6)
Seroconversion	73, 57%	37, 57%	1, 2%
<b>Neutralization antibodies to pseudovirus</b>			
Male	n=126	n=64	n=64
GMT	71.3 (58.0-87.7)	52.5 (39.2-70.3)	5.5 (4.9-6.2)
Seroconversion	110, 87%	53, 83%	1, 2%
Female	n=127	n=65	n=62
GMT	52.9 (43.0-65.1)	58.2 (44.0-77.1)	5.5 (4.9-6.2)
Seroconversion	104, 82%	54, 83%	0

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Data are mean (95% CI) or n (%). GMT = geometric mean antibody titer. RBD = receptor binding domain. Seroconversion was defined as at least a four-fold increase in post-vaccination titre from baseline. All the comparisons across the three treatment groups in terms of the above measurements show significant difference, with p values less than 0.0001, respectively. \* dose group of  $1 \times 10^{11}$  vp vs. dose group of  $5 \times 10^{10}$  vp,  $P=0.0068$ . ‡ dose group of  $1 \times 10^{11}$  vp vs. dose group of  $5 \times 10^{10}$  vp,  $P=0.0047$ . § dose group of  $1 \times 10^{11}$  vp vs. dose group of  $5 \times 10^{10}$  vp,  $P=0.0041$ . vp=viral particles

**Appendix 8. Stratified analyses of the T cell responses based on the age and sex measured by IFN  $\gamma$ -ELISpot.**



- (A) The number of specific T cells with secretion of IFN $\gamma$  at days 0, and 28 in all participants, and stratified by age. vp=viral particles
- (B) The number of specific T cells with secretion of IFN $\gamma$  at days 0, and 28 in all participants, and stratified by sex.

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**Appendix 9. Proportion of participants with either seroconversion of neutralizing antibodies to live SARS-CoV-2 or a positive T cell response measured by INF- $\gamma$  ELISpot at day 28 post-vaccination.**

		<b>Vaccine at <math>1 \times 10^{11}</math> vp</b>	<b>Vaccine at <math>5 \times 10^{10}</math> vp</b>	<b>Placebo</b>	<b>Total</b>
		<b>(n=253)</b>	<b>(n=129)</b>	<b>(n=126)</b>	<b>(n=508)</b>
<b>Day 28 post-vaccination</b>					
<b>Seroconversion</b>	<b>n (%)</b>	241 (95%)	118 (91%)	1 (1%)	360 (71%)
<b>Seroconversion rate CI</b>	<b>95% CI</b>	92%~97%	85%~95%	0.1%~4%	67%~75%

Data are n (%) or 95% CI. A positive antibody response (seroconversion) was defined as at least a 4-fold increase in post-vaccination titer from baseline. The ELISpot T cell responses were considered positive if at least 4-fold increase in the numbers of IFN- $\gamma$ -secreting T cells was found post-vaccination compared to the baseline. vp=viral particles

**Appendix 10. Logistic regression analysis of the incidence of fever with the baseline characters, vaccine dose and pre-existing Ad5 antibodies.**

Model parameters	Estimates	P value	OR	
			Point estimates	95% CI by Wald
<b>Intercept</b>	1.47	0.0021		
<b>Dose group of <math>1 \times 10^{11}</math> vp</b>	0.97	0.0012	2.64	1.47-4.76
<b>Placebo group</b>	-0.80	0.052	0.45	0.20-1.01
<b>Age</b>	-0.06	<0.0001	0.94	0.92-0.96
<b>Sex</b>	-0.53	0.030	0.59	0.36-0.95
<b>Pre-existing Ad5 antibodies (&gt;1:200)</b>	-1.55	<0.0001	0.21	0.13-0.35

The occurrence of adverse reactions (fever) is the dependent variable. The independent variables are the dose group (the dose group of  $5 \times 10^{10}$  vp as the reference), age (continuous variable), sex (female as reference), and the level of Ad5 antibodies pre-vaccination ( $\leq 200$  as reference) included in a multivariable analysis. vp=viral particles

**Appendix 11. List of severe (grade 3) adverse reactions reported within 28 days of follow-up.**

<b>ID of participants</b>	<b>Dose group</b>	<b>Symptom</b>	<b>Grade</b>	<b>Start time</b>	<b>Resolve time</b>	<b>Treatment</b>
<b>007*</b>	Placebo	Muscle strain	3	Day 16 after vaccination	72h	Outpatient treatment
<b>009</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	24h	No treatment
<b>013</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	24h	Self-purchased medicine
<b>019</b>	1×10 <sup>11</sup> vp	Swelling	3	Day 0 after vaccination	48h	No treatment
<b>051</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	24h	No treatment
<b>054</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	48h	Self-purchased medicine
<b>059</b>	1×10 <sup>11</sup> vp	Fatigue	3	Day 1 after vaccination	<24h	No treatment
<b>062</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	24h	No treatment
<b>067</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	24h	No treatment
<b>075</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	<24h	Self-purchased medicine
<b>104</b>	5×10 <sup>10</sup> vp	Fever	3	Day 1 after vaccination	<24h	No treatment
<b>126</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	<24h	No treatment
<b>143</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	<24h	Self-purchased medicine
<b>162</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	48h	Self-purchased medicine
<b>164</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	24h	No treatment
<b>183*</b>	Placebo	Buccal ulceration	3	Day 21 after vaccination	144h	Outpatient treatment
		Oropharyngeal pain	3	Day 17 after vaccination	168h	Self-purchased medicine
<b>186</b>	1×10 <sup>11</sup> vp	Induration	3	Day 1 after vaccination	96h	No treatment
<b>197</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	96h	Self-purchased medicine
<b>202</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	48h	Self-purchased medicine
<b>211</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	24h	Self-purchased medicine
<b>216</b>	1×10 <sup>11</sup> vp	Induration	3	Day 1 after vaccination	72h	No treatment



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<b>217</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	48h	Self-purchased medicine
		Headache	3	Day 1 after vaccination	96h	No treatment
<b>234</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	72h	No treatment
<b>240</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	48h	No treatment
<b>272</b>	1×10 <sup>11</sup> vp	Fever	3	Day 1 after vaccination	48h	Self-purchased medicine
		Muscle pain	3	Day 1 after vaccination	24h	No treatment
		Joint pain	3	Day 1 after vaccination	48h	No treatment
		Dyspnea	3	Day 1 after vaccination	24h	No treatment
		Insomnia	3	Day 1 after vaccination	24h	No treatment
		Headache	3	Day 1 after vaccination	24h	No treatment
<b>436</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	48h	Self-purchased medicine
<b>473</b>	1×10 <sup>11</sup> vp	Fever	3	Day 0 after vaccination	48h	No treatment

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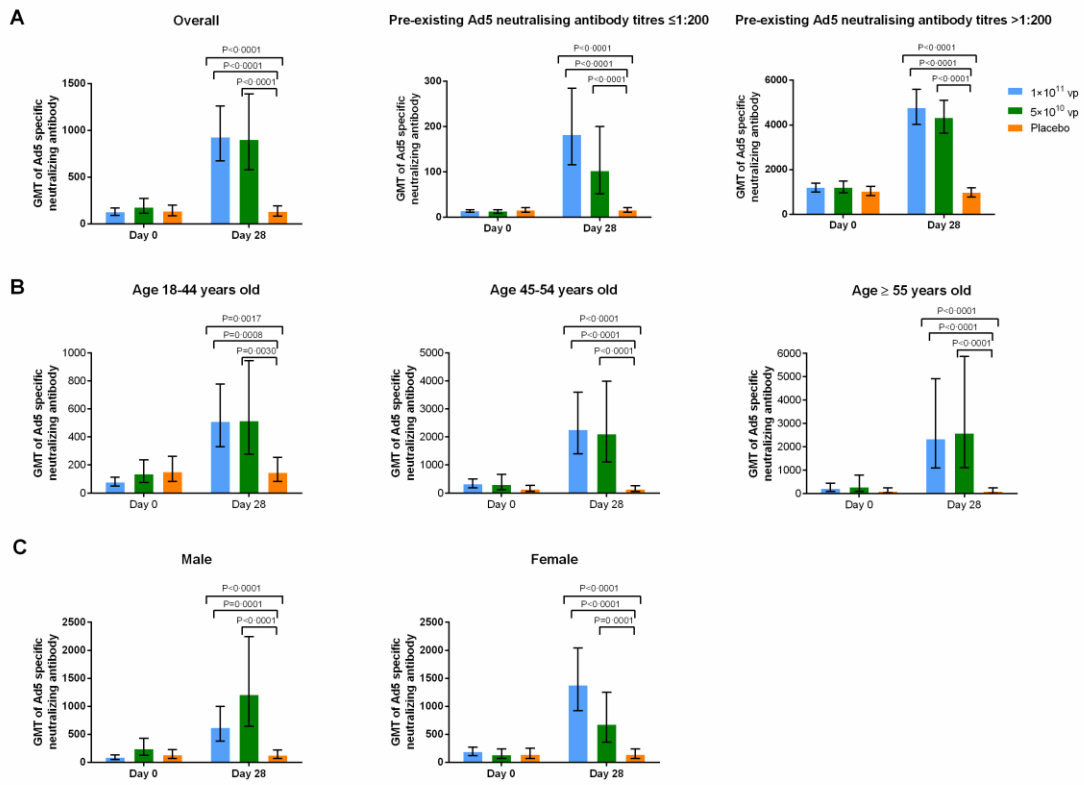
\*The adverse reactions of these participants were not considered to be related to the vaccine. vp=viral particles

**Appendix 12. Unsolicited adverse reactions within 14 days after vaccination.**

	Vaccine at 1×10 <sup>11</sup> vp (n=253)	Vaccine at 5×10 <sup>10</sup> vp (n=129)	Placebo (n=126)	P value*
<b>Unsolicited injection-site adverse reactions within 14 days</b>				
Hemorrhage	1 (<1%)	1 (1%)	0	1·0
Muscle swelling	3 (1%)	2 (2%)	1 (1%)	1·0
<b>Unsolicited systemic adverse reactions within 14 days</b>				
Backache	1 (<1%)	0	1 (1%)	0·75
Coryza	0	0	1 (1%)	0·25
Earache	1 (<1%)	0	0	1·0
Noninfective gingivitis	1 (<1%)	0	0	1·0
Abdominal distress	1 (<1%)	0	0	1·0
Abdominal distension	1 (<1%)	0	0	1·0
Hypoaesthesia	0	1 (1%)	0	0·50
Joint swelling	0	1 (1%)	0	0·50
Muscular weakness	1 (<1%)	0	1 (1%)	0·75
Expectoration	1 (<1%)	0	0	1·0
Thirst	0	0	1 (1%)	0·25
Hypoesthesia oral	2 (1%)	0	0	0·75
Buccal ulceration	1 (<1%)	0	0	1·0
Oral herpes	1 (<1%)	0	0	1·0
Lymph node pain	1 (<1%)	0	0	1·0
Sniffles	1 (<1%)	0	0	1·0
Insomnia	1 (<1%)	0	0	1·0
Grade 3 insomnia	1 (<1%)	0	0	1·0
Somnolence	1 (<1%)	1 (1%)	1 (1%)	1·0
Dizziness	3 (1%)	2 (2%)	1 (1%)	1·0
Palpitation	1 (<1%)	0	0	1·0
Musculoskeletal chest pain	1 (<1%)	0	0	1·0
Chest pain	0	0	1 (1%)	0·25
Axillary pain	1 (<1%)	0	0	1·0
Faeces hard	0	0	1 (1%)	0·25
Aching in limb	1 (<1%)	0	0	1·0

Data are n (%). Any refers to all the participants with any grade adverse reactions or events. Adverse reactions and events were graded according to the scale issued by the China State Food and Drug Administration. Grade 3=severe (ie, prevented activity). \*Calculated with  $\chi^2$  test or Fisher's exact test. vp=viral particles

**Appendix 13. Geometric mean titres of Ad5 neutralising antibodies at days 0 and 28 post-vaccination.**



- (A) GMT of Ad5 neutralising antibodies at days 0 and 28 post-vaccination in all participants, and stratified by pre-existing Ad5 neutralising antibody titres. vp=viral particles
- (B) GMT of Ad5 neutralising antibodies at days 0 and 28 post-vaccination stratified by age.
- (C) GMT of Ad5 neutralising antibodies at days 0 and 28 post-vaccination stratified by sex. GMT=geometric mean titre. Ad5=adenovirus type-5.