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Supplementary information

Immunogenicity and safety of the CoronaVac inactivated vaccine in patients with autoimmune rheumatic diseases: a phase 4 trial

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Supplementary Table 1. Bonferroni's multiple comparisons of neperian logarithmic (ln)-transformed means of anti-SARS-CoV-2 S1/S2 IgG titers before (D0) and after the first (D28) and second (D69) doses of CoronaVac vaccination in autoimmune rheumatic diseases (ARD) and Control Group (CG).

Group/ Evaluation	Comparisons	Mean difference	Std. Error	df	p	95% CI	
						Lower	Upper
ARD, n=859	D0 - D28	-0.83	0.03	1	<0.001	-0.90	-0.75
	D0 - D69	-2.49	0.06	1	<0.001	-2.67	-2.32
	D28 - D69	-1.67	0.05	1	<0.001	-1.82	-1.51
CG, n=179	D0 - D28	-1.52	0.08	1	<0.001	-1.77	-1.27
	D0 - D69	-3.39	0.17	1	<0.001	-3.88	-2.90
	D28 - D69	-1.87	0.15	1	<0.001	-2.31	-1.43
D0	CG - ARD	0.01	0.04	1	>0.999	-0.10	0.12
D28	CG - ARD	0.70	0.10	1	<0.001	0.41	1.00
D69	CG - ARD	0.91	0.18	1	<0.001	0.37	1.45

Data regarding IgG titers of patients with ARD (n=859) and CG (n=179) were analyzed using ANOVA with repeated measures and 2 factors [2 groups (ARD vs. CG), at 3 time points (D0, D28 and D69)], followed by Bonferroni's multiple comparisons at neperian logarithm (ln)-transformed data. Tests were always two-sided. The mean behavior of the neperian logarithm (ln)-transformed IgG titers was different in ARD and CG groups at D28 ($p<0.001$) and D69 ($p<0.001$). Mean titers increased at each time point for ARD ($p<0.001$) and CG ($p<0.001$). At D28 and D69 evaluations, ARD patients presented lower mean titers than CG ($p<0.001$). ARD and CG were comparable only at D0 ($p>0.999$).

Supplementary Table 2. Multiple logistic regression analyses of baseline risk factors for anti-SARS-CoV-2 S1/S2 IgG antibodies seroconversion (SC) and neutralizing antibodies (NAb) positivity after two doses of CoronaVac vaccination in 859 patients with autoimmune rheumatic diseases (ARD)

	Seroconversion (Anti-SARS-CoV-2-S1/S2 IgG)			NAb positivity		
	OR	95% CI	*p*	OR	95% CI	CI
Age ≥ 60years	0.51	0.36-0.74	<0.001	0.65	0.46-0.91	0.011
Female sex	0.99	0.66-1.51	0.978	-	-	-
Caucasian race	0.77	0.55-1.08	0.125	0.75	0.56-1.01	0.057
CIA	-	-	-	0.72	0.49-1.06	0.095
Hydroxychloroquine	-	-	-	1.22	0.85-1.77	0.285
Sulfasalazine	1.86	0.89-3.91	0.101	1.41	0.80-2.49	0.235
Prednisone	0.40	0.28-0.56	<0.001	0.48	0.35-0.65	<0.001
Methotrexate	0.42	0.29-0.61	<0.001	0.67	0.47-0.95	0.024
Mycophenolate mofetil	0.15	0.09-0.24	<0.001	0.33	0.21-0.53	<0.001
Cyclosporine	-	-	-	0.30	0.06-1.59	0.151
TNFi	0.41	0.26-0.64	<0.001	-	-	-
Abatacept	0.24	0.13-0.46	<0.001	0.69	0.36-1.30	0.247
Rituximab	0.34	0.13-0.93	0.036	0.28	0.09-0.87	0.028
Belimumab	0.74	0.32-1.71	0.484	-	-	-
Secukinumab	2.80	0.62-12.67	0.182	2.17	0.86-5.43	0.099

Odds ratio (OR) and 95% confidence interval (CI) for each variable included in the logistic model are presented. Two separate multivariate logistic regression analyses were performed using as dependent variables seroconversion of anti-SARS-CoV-2 IgG or positivity of NAb at D69 (primary endpoints) for the 859 patients with autoimmune rheumatic diseases (ARD) included in immunogenicity analyses. Dependent variables included at each model corresponded to those with p<0.2 in each univariate analysis (Table 4). CIA – chronic inflammatory arthritis (rheumatoid arthritis, axial spondyloarthritis and psoriatic arthritis).
TNFi – tumor necrosis factor inhibitors.