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Supplementary appendix

This appendix formed part of the original submission. We post it as supplied by the authors.

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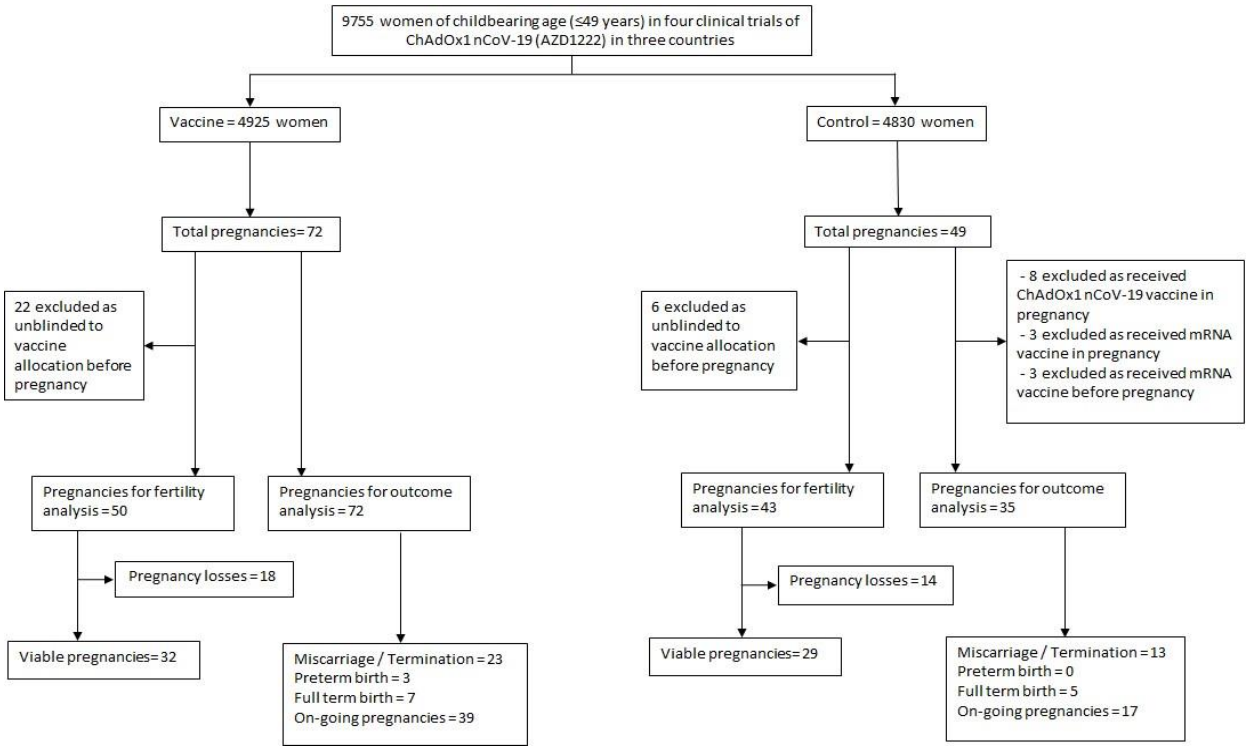
SUPPLEMENTARY MATERIAL

Supplementary Figure 1: Study flowchart



Supplementary Table 1. Baseline characteristics of the 121 pregnant participants

Characteristic	Vaccine (n=72)	Control (n=35)	Exclusions[1] (n=14)	ALL (n=121)	Standardized Difference[2]
Age at first assessment					
19 - 31 years	32 (44·4%)	23 (65·7%)	6 (42·9%)	61 (50·4%)	
32 - 45 years	40 (55·6%)	12 (34·3%)	8 (57·1%)	60 (49·6%)	0·44
Median (IQR)	32 (9)	29 (9)	34 (12)	31 (10)	
Mean (sd)	31·6 (5.9)	29·2 (6·5)	34·1 (6·5)	31·2 (6·3)	0·39
Min - maximum	19 - 43	20 - 45	25 - 43	19 - 45	
BMI					
mean (SD)	26·4 (5.8)	25·9 (5·5)	25·2 (4·6)	26·1 (5·6)	0·09
Min - maximum	17·5-41·3	19·2-40·6	16·5-33·6	16·5 - 41·3	
Sites					
UK	30 (41·7%)	15 (42·9%)	11 (78·6%)	56 (46·3%)	0·15
Brazil	29 (40·3%)	11 (31·4%)	2 (14·3%)	42 (34·7%)	
South Africa	13 (18·1%)	9 (25·7%)	1 (7·1%)	23 (19·0%)	
Ethnicity					
White	43 (59.7%)	19 (54·3%)	11 (786%)	73 (60·3%)	0·11
Black	14 (19·4%)	10 (28·6%)	2 (14·3%)	26 (21·5%)	
Asian	5 (6·9%)	1 (2·9%)	0 (0%)	6 (5·0%)	
Hispanic	7 (9·7%)	2 (5·7%)	0 (0%)	9 (7·4%)	
Mixed/other	3 (4·2%)	3 (8·6%)	1 (7·1%)	7 (5·8%)	
Co-morbidities present	14 (19·4%)	9 (25·7%)	2 (14·3%)	25 (20·7%)	-0·15
Current smoker	9 (12·5%)	4 (11·4%)	2 (14·3%)	15 (12·4%)	0·03
Current alcohol use	58 (80·6%)	22 (62·9%)	11 (78·6%)	91 (75·2%)	0·40
Recreational drug use	0 (0%)	0 (0%)	0 (0%)	0 (0%)	
Contraception at pregnancy notification					
OCP	18 (25·0%)	11 (31·4%)	1 (7·1%)	30 (24·8%)	
Barrier	23 (31·9%)	7 (20·0%)	4 (28·6%)	34 (28·1%)	
IUD	1 (1·4%)	2 (5·7%)	1 (7·1%)	4 (3·3%)	
Injectable	3 (4·2%)	1 (2·9%)	1 (7·1%)	5 (4·1%)	
Nil	27 (37·5%)	14 (40·0%)	7 (50·0%)	48 (39·7%)	-0·05
Number of days from 1st dose (control/vaccine) to pregnancy					
Median (IQR)	109·5 (162·5)	121 (148)	----	117 (157)	
Mean (SD)	126·7 (94·9)	130·6 (93·6)	----	127·9 (94·1)	-0·04
Min - Maximum	0 - 363	2 - 322	----	0 - 363	

1. Exclusions (n=14). These comprised 11 individuals in the control group who subsequently became pregnant and were later unblinded and went on to receive either ChAdOx1 nCoV-19 or an mRNA vaccine as part of the national rollout (ie were vaccinated during pregnancy) and 3 individuals who received an mRNA vaccine before pregnancy. These 14 were excluded from the pregnancy outcome analysis (Table 2).

2. Standardised difference (Vaccine-Control) for means were computed as Hedges' *g*, and between two **proportions** were calculated as the difference (p1-p2) divided by the standard error of the difference. Where the covariate was multinomial, the categories were simplified to binomial, which were: **ethnicity** (white, Other), and **contraception at pregnancy notification** (no, yes). Brazil was excluded from covariate **study site,** leaving "UK" & "South Africa", in line with the covariate adjusted for in the Poisson regression (Supplementary Table 3).

Supplementary Table 2. Fertility rates in ChAdOx1 nCoV19 vaccinated women compared to controls, by individual site.

Site	**Parameter**	**Vaccine**	**Control***	**Fertility rate ratio Vaccine/Control (95% CI)**	Exact p value
UK	Women of child-bearing age (≤49yrs)	2402	2376		
	Pregnant women	23	23		
	Fertility Rate	*0·0096*	*0·0097*	0·99 (0·56, 1·76)	>0·999
	Viable pregnancies**	13	15		
	Fertility Rate (viable pregnancies)	*0·0054*	*0·0063*	0·86 (0·41, 1·80)	0·709
Brazil	Women of child-bearing age (≤49yrs)	2154	2083		
	Pregnant women	15	10		
	Fertility Rate	*0·0070*	*0·0048*	1·45 (0·65, 3·22)	0·425
	Viable pregnancies**	11	7		
	Fertility Rate (viable pregnancies)	*0·0051*	*0·0034*	1·52 (0·59, 3·91)	0·481
South Africa	Women of child-bearing age (≤49yrs)	369	371		
	Pregnant women	12	10		
	Fertility Rate	*0·0325*	*0·0270*	1·21 (0·53, 2·76)	0·672
	Viable pregnancies**	8	7		
	Fertility Rate (viable pregnancies)	*0·0217*	*0·0189*	1·15 (0·42, 3·14)	0·801
All Sites	Women of child-bearing age (≤49yrs)	4925	4830		
	Pregnant women	50	43		
	Fertility Rate	*0·0102*	*0·0089*	1·14 (0·76, 1·71)	0·534
	Viable pregnancies**	32	29		
	Fertility Rate (viable pregnancies)	*0·0065*	*0·0060*	1·08 (0·66, 1·79)	0·798

28 pregnant women (6 controls & 22 vaccinees) were excluded from this fertility analysis because they were unblinded to vaccine allocation before becoming pregnant. *11 women vaccinated during pregnancy were included in the controls (8 received ChAdOx1 nCoV-19, 3 mRNA vaccines); all 11 were unblinded after becoming pregnant. **"Viable pregnancies" did not include pregnant women who had a termination or miscarriage.

Supplementary Table 3: Pregnancy outcome "Miscarriage", excluding the data from Brazil.

Main exposure	Main outcome Miscarriage	Adjusted risk ratio Vaccine/Control)	95% CI for Risk ratio	p-value
Control	5/24 (21%)	1·00 (referent)		
Vaccine	6/43 (14%)	0·84	0·24, 2·90	0·785

Estimate of adjusted risk ratio is from a multivariable Poisson regression model with robust variance estimation. Adjustment was made for effect of the following potential confounders: Age; BMI; Ethnicity (white, black, other); Country (UK, S. Africa); Comorbidity (no, yes); Smoking (no, yes); Alcohol use (no, yes).

Statistical Methods

Analyses were performed using Stata software version 17 (StataCorp LP, College Station, TX).

Risk or rate ratios were computed with 95% confidence intervals. All exact p-values were 2-sided, from Fisher's exact test. Estimate of adjusted risk ratio (Supplementary Table 3) were from a multivariable Poisson regression for a binary outcome (miscarriage) with robust variance estimation and an offset, and adjustment for: Age; BMI; Ethnicity (white, black, other); Country (UK, S. Africa); Comorbidity (no, yes); Smoking (no, yes); Alcohol use (no, yes).

Standardized differences (in Supplementary Table 1)
Standardized difference (Vaccine-Control) between two means were computed as Hedges' *g,* taking into account the difference in sample sizes, and between two proportions were calculated as the difference (p1-p2) divided by the standard error of the difference. Where the covariate was multinomial, the categories were simplified to binomial, which were: **ethnicity** (white, Other), and **contraception at pregnancy notification** (no, yes). Brazil was excluded from covariate **study site,** leaving "UK" & "South Africa", in line with the covariate adjusted for in the Poisson regression (Supplementary Table 3)

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