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Supplementary appendix 2

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Appendix to Effect of BCG vaccination against *Mycobacterium tuberculosis* infection in adult Brazilian health-care workers: a nested clinical trial

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Supplementary Results

Supplementary Table 1. The primary analysis of QuantiFERON results stratified by study arm in the intention-to-treat population (regardless of Month 12 QFT performed).*

	BCG group	Placebo group	RR (95% CI)	p-value
Primary outcome				
QFT conversion (positivity threshold ≥0·35 IU/mL)	34/1129 (3·0)	32/1140 (2·8)	1·09 (0·66 to 1·77)	0·727
Secondary outcome				
Sustained conversion (positivity threshold ≥0·35 IU/mL)	15/1129 (1·3)	19/1140 (1·7)	0·81 (0·41 to 1·60)	0·546
Exploratory outcomes				
QFT conversion (positivity threshold ≥0·70 IU/mL)	15/1129 (1·3)	13/1140 (1·1)	1·17 (0·56 to 2·51)	0·671
QFT conversion (positivity threshold ≥2·00 IU/mL)	6/1129 (0·5)	5/1140 (0·4)	1·21 (0·37 to 3·95)	0·757
QFT conversion (positivity threshold ≥4·00 IU/mL)	2/1129 (0·2)	3/1140 (0·3)	0·66 (0·11 to 3·97)	0·654
QFT conversion (baseline QFT <0·20 IU/mL, and positivity threshold ≥0·35 IU/mL)	22/1078 (2·0)	23/1093 (2·1)	0·99 (0·55 to 1·78)	0·971

Data are n/N (%), unless otherwise specified. *All analyses were done in the intention-to-treat population. QFT=QuantiFERON-TB Gold.

Supplementary Table 2. The secondary analysis of QuantiFERON results stratified by study arm in the intention-to-treat population (Month 12 QFT available).*

	BCG group	Placebo group	RR (95% CI)	p-value
Primary outcome				
QFT conversion (positivity threshold ≥0·35 IU/mL)	34/996 (3·4)	32/989 (3·2)	1·05 (0·65 to 1·71)	0·833
Secondary outcome				
Sustained conversion (positivity threshold ≥0·35 IU/mL)	15/996 (1·5)	19/989 (1·9)	0·79 (0·40 to 1·56)	0·490
Exploratory outcomes				
QFT conversion (positivity threshold ≥0·70 IU/mL)	15/996 (1·5)	13/989 (1·3)	1·14 (0·54 to 2·40)	0·727
QFT conversion (positivity threshold ≥2·00 IU/mL)	6/996 (0·6)	5/989 (0·5)	1·14 (0·35 to 3·75)	0·825
QFT conversion (positivity threshold ≥4·00 IU/mL)	2/996 (0·2)	3/989 (0·3)	0·62 (0·10 to 3·73)	0·611
QFT conversion (baseline QFT <0·20 IU/mL, and positivity threshold ≥0·35 IU/mL)	22/957 (2·3)	23/950 (2·4)	0·95 (0·53 to 1·72)	0·873

Data are n/N (%), unless otherwise specified. *All analyses were done in the intention-to-treat population. QFT=QuantiFERON-TB Gold.

Supplementary Table 3. The secondary analysis of QuantiFERON results stratified by study arm in the intention-to-treat population (regardless of Month 12 QFT performed).*

	BCG group	Placebo group	RR (95% CI)	p-value
Primary outcome				
QFT conversion (positivity threshold ≥0·35 IU/mL)	34/1129 (3·0)	32/1140 (2·8)	1·08 (0·66 to 1·75)	0·762
Secondary outcome				
Sustained conversion (positivity threshold ≥0·35 IU/mL)	15/1129 (1·3)	19/1140 (1·7)	0·81 (0·41 to 1·60)	0·551
Exploratory outcomes				
QFT conversion (positivity threshold ≥0·70 IU/mL)	15/1129 (1·3)	13/1140 (1·1)	1·17 (0·56 to 2·46)	0·681
QFT conversion (positivity threshold ≥2·00 IU/mL)	6/1129 (0·5)	5/1140 (0·4)	1·17 (0·36 to 3·85)	0·792
QFT conversion (positivity threshold ≥4·00 IU/mL)	2/1129 (0·2)	3/1140 (0·3)	0·64 (0·11 to 3·86)	0·634
QFT conversion (baseline QFT <0·20 IU/mL, and positivity threshold ≥0·35 IU/mL)	22/1078 (2·0)	23/1093 (2·1)	0·98 (0·54 to 1·76)	0·940

Data are n/N (%), unless otherwise specified. *All analyses were done in the intention-to-treat population. QFT=QuantiFERON-TB Gold.

Supplementary Table 4. The primary analysis of QuantiFERON results stratified by study arm in the per-protocol population (Month 12 QFT available).*

	BCG group	Placebo group	RR (95% CI)	p-value
Primary outcome				
QFT conversion (positivity threshold ≥0·35 IU/mL)	34/995 (3·4)	32/985 (3·2)	1·06 (0·66 to 1·73)	0·799
Secondary outcome				
Sustained conversion (positivity threshold ≥0·35 IU/mL)	15/995 (1·5)	19/985 (1·9)	0·80 (0·40 to 1·57)	0·504
Exploratory outcomes				
QFT conversion (positivity threshold ≥0·70 IU/mL)	15/995 (1·5)	13/985 (1·3)	1·15 (0·54 to 2·45)	0·716
QFT conversion (positivity threshold ≥2·00 IU/mL)	6/995 (0·6)	5/985 (0·5)	1·17 (0·36 to 3·85)	0·790
QFT conversion (positivity threshold ≥4·00 IU/mL)	2/995 (0·2)	3/985 (0·3)	0·64 (0·11 to 3·84)	0·632
QFT conversion (baseline QFT <0·20 IU/mL, and positivity threshold ≥0·35 IU/mL)	22/956 (2·3)	23/946 (2·4)	0·96 (0·53 to 1·73)	0·896

Data are n/N (%), unless otherwise specified. *All analyses were done in the per-protocol population. QFT=QuantiFERON-TB Gold.

Supplementary Table 5. The primary analysis of QuantiFERON results stratified by study arm in the per-protocol population (regardless of Month 12 QFT performed).*

	BCG group	Placebo group	RR (95% CI)	p-value
Primary outcome				
QFT conversion (positivity threshold ≥0·35 IU/mL)	34/1127 (3·0)	32/1136 (2·8)	1·09 (0·67 to 1·77)	0·731
Secondary outcome				
Sustained conversion (positivity threshold ≥0·35 IU/mL)	15/1127 (1·3)	19/1136 (1·7)	0·81 (0·41 to 1·60)	0·542
Exploratory outcomes				
QFT conversion (positivity threshold ≥0·70 IU/mL)	15/1127 (1·3)	13/1136 (1·1)	1·17 (0·56 to 2·50)	0·672
QFT conversion (positivity threshold ≥2·00 IU/mL)	6/1127 (0·5)	5/1136 (0·4)	1·20 (0·37 to 3·95)	0·758
QFT conversion (positivity threshold ≥4·00 IU/mL)	2/1127 (0·2)	3/1136 (0·3)	0·66 (0·11 to 3·96)	0·654
QFT conversion (baseline QFT <0·20 IU/mL, and positivity threshold ≥0·35 IU/mL)	22/1076 (0·2)	23/1089 (0·3)	0·99 (0·55 to 1·78)	0·968

Data are n/N (%), unless otherwise specified. *All analyses were done in the per-protocol population. QFT=QuantiFERON-TB Gold.

Supplementary Table 6. The secondary analysis of QuantiFERON results stratified by study arm in the per-protocol population (Month 12 QFT available).*

	BCG group	Placebo group	RR (95% CI)	p-value
Primary outcome				
QFT conversion (positivity threshold ≥0·35 IU/mL)	34/995 (3·4)	32/985 (3·2)	1·05 (0·65 to 1·71)	0·842
Secondary outcome				
Sustained conversion (positivity threshold ≥0·35 IU/mL)	15/995 (1·5)	19/985 (1·9)	0·79 (0·40 to 1·55)	0·339
Exploratory outcomes				
QFT conversion (positivity threshold ≥0·70 IU/mL)	15/995 (1·5)	13/985 (1·3)	1·14 (0·54 to 2·40)	0·731
QFT conversion (positivity threshold ≥2·00 IU/mL)	6/995 (0·6)	5/985 (0·5)	1·14 (0·35 to 3·74)	0·827
QFT conversion (positivity threshold ≥4·00 IU/mL)	2/995 (0·2)	3/985 (0·3)	0·62 (0·10 to 3·72)	0·610
QFT conversion (baseline QFT <0·20 IU/mL, and positivity threshold ≥0·35 IU/mL)	22/956 (2·3)	23/946 (2·4)	0·95 (0·53 to 1·71)	0·867

Data are n/N (%), unless otherwise specified. *All analyses were done in the per-protocol population. QFT=QuantiFERON-TB Gold.

Supplementary Table 7. The secondary analysis of QuantiFERON results stratified by study arm in the per-protocol population (regardless of Month 12 QFT performed).*

	BCG group	Placebo group	RR (95% CI)	p-value
Primary outcome				
QFT conversion (positivity threshold ≥0·35 IU/mL)	34/1127 (3·0)	32/1136 (2·8)	1·08 (0·66 to 1·75)	0·768
Secondary outcome				
Sustained conversion (positivity threshold ≥0·35 IU/mL)	15/1127 (1·3)	19/1136 (1·7)	0·81 (0·41 to 1·60)	0·545
Exploratory outcomes				
QFT conversion (positivity threshold ≥0·70 IU/mL)	15/1127 (1·3)	13/1136 (1·1)	1·17 (0·56 to 2·46)	0·682
QFT conversion (positivity threshold ≥2·00 IU/mL)	6/1127 (0·5)	5/1136 (0·4)	1·17 (0·36 to 3·84)	0·794
QFT conversion (positivity threshold ≥4·00 IU/mL)	2/1127 (0·2)	3/1136 (0·3)	0·64 (0·11 to 3·85)	0·633
QFT conversion (baseline QFT <0·20 IU/mL, and positivity threshold ≥0·35 IU/mL)	22/1076 (0·2)	23/1089 (0·3)	0·98 (0·54 to 1·76)	0·936

Data are n/N (%), unless otherwise specified. *All analyses were done in the per-protocol population. QFT=QuantiFERON-TB Gold.