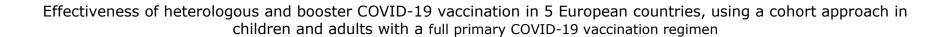
Covid Vaccines Effectiveness (CoVE)



Specific Contract No 01 implementing framework contract No EMA/2020/46/TDA/L5.06.

EU PAS Register No: <u>EUPAS47725</u>

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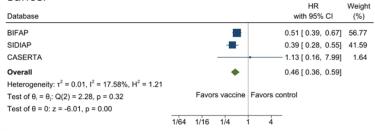
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Severe COVID-19 in adults - Booster vaccination schemes

Severe COVID-19 infection

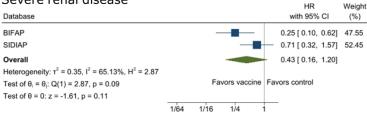
HOMOLOGOUS vs NO BOOSTER

Cancer



Random-effects REML model

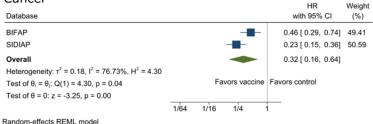
Severe renal disease



Random-effects REML model

HETEROLOGOUS (homologous primary) vs NO BOOSTER

Cancer

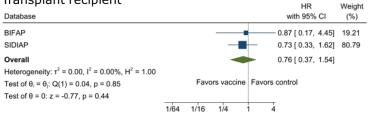


Immunodeficiency

Database				HR with 95% CI	Weight (%)
BIFAP				0.37 [0.32, 0.43]	73.32
SIDIAP			-	0.40 [0.31, 0.52]	25.85
CASERTA			-	0.22 [0.05, 0.98]	0.83
Overall			•	0.38 [0.33, 0.43]	
Heterogeneity: $r^2 = 0.00$, $I^2 = 0.00\%$, $H^2 = 1.00$ Test of $\theta_i = \theta_j$: Q(2) = 0.74, p = 0.69		Fav	vors vaccine	Favors control	
Test of $\theta = 0$: $z = -14.06$, $p = 0.00$	1/64	1/16	1/4	1	

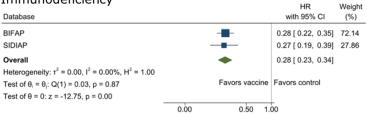
Random-effects REML model

Transplant recipient



Random-effects REML model

Immunodeficiency

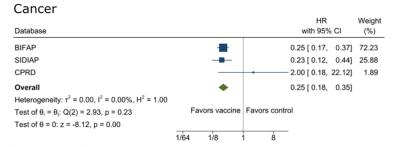


Random-effects REML model

Death with COVID-19 in adults - Booster vaccination schemes

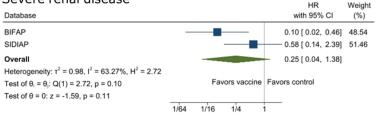
Death with COVID-19 infection

HOMOLOGOUS vs NO BOOSTER



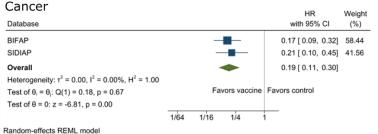
Random-effects REML model

Severe renal disease



Random-effects REML model

HETEROLOGOUS (homologous primary) vs NO BOOSTER

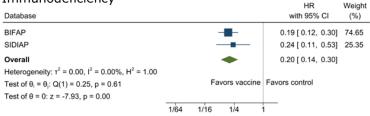


Immunodeficiency

Database		HR with 95% CI	Weight (%)
BIFAP	-	0.29 [0.22, 0.39]	68.31
SIDIAP		0.20 [0.12, 0.34]	29.20
CPRD		0.99 [0.14, 7.00]	2.48
Overall	•	0.27 [0.20, 0.37]	
Heterogeneity: $\tau^2 = 0.02$, $I^2 = 15.29\%$, $H^2 = 1.18$ Test of $\theta_i = \theta_j$: Q(2) = 3.21, p = 0.20 Test of $\theta = 0$: z = -8.30, p = 0.00	Favors vaccine	Favors control	
rest or 6 – 0. 2 – -6.50, p – 0.00	1/64 1/16 1/4	1 4	

Random-effects REML model

Immunodeficiency

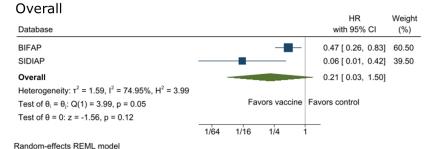


Random-effects REML model

Severe COVID-19 in children (5-14 years old)

CHILDREN (5-14 years old)

VACCINATED vs NO VACCINATED



Random-effects REML model

Delta variant period

Test of $\theta_i = \theta_i$: Q(1) = 2.61, p = 0.11

Test of $\theta = 0$: z = -1.86, p = 0.06

Heterogeneity: $\tau^2 = 1.08$, $I^2 = 61.69\%$, $H^2 = 2.61$

Database

BIFAP

SIDIAP

Overall

HR

with 95% CI

0.18 [0.03, 1.10]

Favors vaccine Favors control

1/16 1/4

0.39 [0.12, 1.28] 58.68

0.06 [0.01, 0.42] 41.32

Weight

(%)

Severe COVID-19 - summary

Comparison and population	Adjusted HR (95% CI)	Adjusted VE (95% CI)		
Homo-primary vs Non-vaccinated among children without previous Covid-19 infection				
Overall	0.21 (0.03-1.50)	79% (-50 to 97%)		
Delta	0.18 (0.03-1.10)	82% (-10 to 97%)		
Omicron (only BIFAP-ES)	NA	NA		
Homo-primary + Homo-Booster vs Homo-primary + No Booster among adults without previous Covid-19 infection				
Patients with immunodeficiency or immunosuppressant	0.38 (0.33-0.43)	62% (57 to 67%)		
Patients with cancer	0.46 (0.36-0.59)	54% (41 to 64%)		
Patients receiving transplants	0.76 (0.37-1.54)	24% (-54 to 63%)		
Patients with severe renal disease	0.43 (0.16-1.2)	57% (-20 to 84%)		
Patients with Down Syndrome	no data			
Homo-primary + Hetero-Booster vs Homo-primary + No Booster among adults without previous Covid-19 infection				
Patients with immunodeficiency or immunosuppressant	0.28 (0.23-0.34)	72% (66 to 77%)		
Patients with cancer	0.32 (0.16-0.64)	68% (36 to 84%)		
Patients receiving transplants	no data			
Patients with severe renal disease (only BIFAP-ES)	0.67 (0.16-2.87)	33% (-187 to 84%)		
Patients with Down Syndrome	no data			
Hetero-primary + Any Booster vs Hetero-primary + No Booster among adults without previous Covid-19 infection				
Patients with immunodeficiency or immunosuppressant	no data			
Patients with cancer	no data			
Patients receiving transplants	no data			
Patients with severe renal disease	no data			
Patients with Down Syndrome	no data			

Death with COVID-19 - summary

Comparison and population	Adjusted HR (95% CI)	Adjusted VE (95% CI)		
Homo-primary vs Non-vaccinated among children without previous Covid-19 infection				
Overall	No data	No data		
Homo-primary + Homo-Booster vs Homo-primary + No Booster among adults without previous Covid-19 infection				
Patients with immunodeficiency or immunosuppressant	0.27 (0.20-0.37)	73% (63 to 80%)		
Patients with cancer	0.25 (0.18-0.35)	75% (65 to 82%)		
Patients receiving transplants	no data			
Patients with severe renal disease	0.25 (0.04-1.38)	75% (-38 to 96%)		
Patients with Down Syndrome	no data			
Homo-primary + Hetero-Booster vs Homo-primary + No Booster among adults without previous Covid-19 infection				
Patients with immunodeficiency or immunosuppressant	0.20 (0.14-0.30)	80% (70 to 86%)		
Patients with cancer	0.19 (0.11-0.30)	81% (70 to 89%)		
Patients receiving transplants	no data			
Patients with severe renal disease	no data			
Patients with Down Syndrome	no data			
Hetero-primary + Any Booster vs Hetero-primary + No Booster among adults without previous Covid-19 infection				
Patients with immunodeficiency or immunosuppressant	no data			
Patients with cancer	no data			
Patients receiving transplants	no data			
Patients with severe renal disease	no data			
Patients with Down Syndrome	no data			