Aihara, 2015/12/24

HPV vaccine compared to placebo for healthy women

Bibliography: Lu B, et al. Efficacy and safety of prophylactic vaccines against cervical HPV infection and diseases among women: A systematic review and meta-analysis .BMC Infectious Diseases 2011; 11:13

Quality assessment							Summary of findings				
№ of participants (studies) Follow-up	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Overall quality of evidence	Study event rates (%)		Relative effect (95% CI)	Anticipated absolute effects	
							With placebo	With HPV vaccine		Risk with placebo	Risk difference with HPV vaccine
CIN2+ associated with HPV 16 (follow up: range 26 months to 60 months)											
29029 (4 RCTs)	not serious	not serious [1]	not serious	not serious	none	⨁⨁⨁⨁ HIGH	232/14523 (1.6%)	5/14506 (0.0%)	**RR 0.47** (0.36 to 0.61)	**Study population**	
										16 per 1000	**8 fewer per 1000** (10 fewer to 6 fewer)
CIN2+associated with HPV18 (follow up: range 26 months to 60 months)											
28053 (3 RCTs)	not serious	not serious	not serious	not serious	none	⨁⨁⨁⨁ HIGH	53/14030 (0.4%)	8/14023 (0.1%)	**RR 0.16** (0.08 to 0.34)	**Study population**	
										4 per 1000	**3 fewer per 1000** (3 fewer to 2 fewer)
CIN1+ associated with HPV16 (follow up: range 26 months to 60 months)											
21891 (4 RCTs)	not serious	not serious [2]	not serious	not serious	none	⨁⨁⨁⨁ HIGH	174/10969 (1.6%)	67/10922 (0.6%)	**RR 0.43** (0.33 to 0.58)	**Study population**	
										16 per 1000	**9 fewer per 1000** (11 fewer to 7 fewer)
CIN1+ associated with HPV18 (follow up: range 26 months to 60 months)											
28053	not	not serious	not serious	not serious	none	⨁⨁⨁⨁	53/14030	8/14023	**RR 0.16**	**Study population**	

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Quality assessment							Summary of findings				
(3 RCTs)	serious					HIGH	(0.4%)	(0.1%)	(0.08 to 0.34)	4 per 1000	**3 fewer per 1000** (3 fewer to 2 fewer)
Persistent HPV 16 infection >=6mo											
11964 (2 RCTs)	not serious	not serious	not serious	not serious	none	⊕⊕⊕⊕ HIGH	173/5990 (2.9%)	25/5974 (0.4%)	**RR 0.15** (0.10 to 0.23)	**Study population**	
										29 per 1000	**25 fewer per 1000** (26 fewer to 22 fewer)
Persistent HPV 18 infection >=6mo											
12948 (2 RCTs)	not serious	not serious	not serious	not serious	none	⊕⊕⊕⊕ HIGH	69/6492 (1.1%)	16/6456 (0.2%)	**RR 0.24** (0.14 to 0.42)	**Study population**	
										11 per 1000	**8 fewer per 1000** (9 fewer to 6 fewer)
CIN2+ associated with HPV 31/33/35/52/58											
34476 (2 RCTs)	not serious	not serious	not serious	not serious	none	⊕⊕⊕⊕ HIGH	341/17263 (2.0%)	267/17213 (1.6%)	**RR 0.79** (0.67 to 0.92)	**Study population**	
										20 per 1000	**4 fewer per 1000** (7 fewer to 2 fewer)
Persistent infection of HPV 31/33/45/52/58 >=6mo											
20524 (2 RCTs)	not serious	not serious [3]	not serious	not serious	none	⊕⊕⊕⊕ HIGH	1418/10262 (13.8%)	1092/10262 (10.6%)	**RR 0.77** (0.72 to 0.83)	**Study population**	
										138 per 1000	**32 fewer per 1000** (39 fewer to 23 fewer)
Serious adverse event (follow up: range 15 days to 30 days)											

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Quality assessment							Summary of findings				
43856 (7 RCTs)	not serious	not serious	not serious	not serious	none	⊕⊕⊕⊕ HIGH	829/21940 (3.8%)	825/21916 (3.8%)	**RR 1.00** (0.91 to 1.09)	**Study population**	
										38 per 1000	**0 fewer per 1000** (3 fewer to 3 more)
Injection-related serous adverse event (follow up: range 15 days to 30 days)											
43756 (7 RCTs)	not serious	not serious	not serious	not serious	none	⊕⊕⊕⊕ HIGH	5/21840 (0.0%)	15/21916 (0.1%)	**RR 1.82** (0.79 to 4.20)	**Study population**	
										0 per 1000	**0 fewer per 1000** (0 fewer to 1 more)

CI: Confidence interval; **RR:** Risk ratio

1. significant heterogeneity among pooled studies (Cochrane's Q, $p < 0.001$; $I2 = 87\%$).
2. significant heterogeneity among included trials (Cochrane's Q, $p = 0.006$; $I2 = 76\%$)
3. heterogeneity: Cochrane's Q, $p < 0.0001$, $I2 = 94\%$;