

Grade table 6. Safety of Herpes Zoster vaccine in immunocompetent adults ≥60 years

Population: Immunocompetent adults (>60 years)

Intervention: Herpes zoster vaccination

Comparison: Placebo/no intervention

Outcome: Serious adverse events

<i>In immunocompetent adults (60-69 years), what is the incidence of serious adverse events for any dose of herpes zoster vaccination compared to placebo?</i>				
			Rating	Adjustment to rating
Quality Assessment	No. of studies/starting rating		1/ RCT ¹	4
	Factors decreasing confidence	Limitation in study design	None Serious	0
		Inconsistency	None serious	0
		Indirectness	None serious	0
		Imprecision	None Serious	0
		Publication bias	None serious	0
	Factors increasing confidence	Large effect	Not applicable	0
		Dose-response	Not applicable	0
		Antagonistic bias and confounding	Not applicable	0
	Final numerical rating of quality of evidence			4
Summary of Findings	Statement on quality of evidence			We are very confident that the true effect lies close to that of the estimate of effect on health outcome
	Conclusion			Our confidence in the estimate of the effect is high that incidence of serious adverse events following one dose of herpes zoster vaccination in immunocompetent adults (>60 years) compared to placebo is low. Overall few reports and low incidence of serious adverse events in one RCT.

Reference List

Oxman MN, Levin MJ, Johnson GR, Schmader KE, Straus SE, Gelb LD, et al. A vaccine to prevent herpes zoster and postherpetic neuralgia in older adults. N Engl J Med 2005 Jun 2;352(22):2271-84.

Gagliardi AMZ, Silva BNG, Torloni MR, Soares BGO. Vaccines for preventing herpes zoster in older adults 1. Cochrane Database of Systematic Reviews 2012;(10).

¹A Cochrane review (Gagliardi et al. 2012) calculated the risk ratio for serious adverse effects in vaccinees compared to placebo in participants 60-69 years: 1.2 (95% confidence interval (CI): 0.92-1.57) based on data from Oxman et al. 2005, a RCT with low risk of bias and >17 000 study participants.