Table 37: Clinical evidence profile: Staphylococcus vaccine (Staphypan Berna) versus placebo

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Staphylococcus vaccine versus placebo	Control	Relative (95% CI)	Absolute		
Pain: pain on VAS (follow-up 32 weeks; range of scores: unclear; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	no serious imprecision	none	49	49	-	MD 0.3 lower (1.12 lower to 0.52 higher)	⊕⊕OO LOW	CRITICAL
Adverse events (follow-up 32 weeks)												

1	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	very serious[2]	none	28/50 (56%)	26/50 (52%)	RR 1.08 (0.75 to 1.55)	42 more per 1000 (from 130 fewer to 286 more)	⊕OOO VERY LOW	CRITICAL
Symptom scales: clinical global impression of change (follow-up 32 weeks; range of scores: 1-7; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	serious[2]	none	49	49	-	MD 0.7 lower (1.22 to 0.18 lower)	⊕OOO VERY LOW	CRITICAL
Symptom scales: clinical global impression of severity (follow-up 32 weeks; range of scores: 1-7; Better indicated by lower values)												
1	randomised trials	no serious risk of bias	no serious inconsistency	very serious[1]	serious[2]	none	49	49	-	MD 0.3 lower (0.53 to 0.07 lower)	⊕OOO VERY LOW	CRITICAL

[1] The majority of the evidence included an indirect population (downgraded by one increment) or a very indirect population (downgraded by two increments). Populations were downgraded if the ME/CFS diagnostic criteria used did not include PEM as a compulsory feature. Zachrisson 2002 was downgraded twice due to population also meeting diagnostic criteria for fibromyalgia.
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs