

Figure. Modified risk of bias tool.

Domain / Sub-domain		Risk
1. Random sequence generation (selection bias) <i>Additional IPD checks:</i> <i>Check 1: Cumulative number of allocated participants to each treatment arm by date of randomisation.</i> <i>Check 2: Number of randomised infants per day of the week.</i> <i>Check 3: Runs test for randomisation on treatment arm sequence.</i>		Low Unclear High
2. Allocation concealment (selection bias)		Low Unclear High
3. Blinding of participants and personnel (performance bias)		Low Unclear High
Blinding of outcome assessment (detection bias)	4. Infant mortality	Low Unclear High
	5. Delivery room outcomes	Low Unclear High
	6. Beyond delivery room outcomes	Low Unclear High
	7. Long-term outcomes	Low Unclear High
8. Incomplete outcome data (attrition bias) <i>Additional IPD checks:</i> <i>Check 1: Check amount of IPD provided compared to amount expected/reported in publication.</i> <i>Check 2: Rate of missing data in key outcomes by treatment arm.</i> <i>Check 3: Rate of missing data in key long-term outcomes by treatment arm.</i>		Low Unclear High
9. Selective outcome reporting (reporting bias) <i>Not applicable for trials providing IPD¹</i>		Low Unclear High
Other bias	10. General	Low Unclear High
	11. Infant mortality <i>Assessing post-randomisation exclusion of stillbirth or missing mortality data.</i>	Low Unclear High

¹ Tierney J, Riley R, Rydzewska L, Stewart L. Running an IPD Meta-Analysis Project. In: Riley RD, Tierney JF, Stewart LA, editors. Individual participant data meta-analysis: a handbook for healthcare research. John Wiley & Sons; 2021.

Overall Risk of Bias		
<p>High risk if 1 domain/sub-domain is high or 3 or more domains are unclear. Some concerns if 1-2 domains are unclear. Low if all domains are low.</p>		
Group	Overall Risk	Domains used for overall risk
Infant mortality		1, 2, 3, 4, 8, 9, 10, 11
Delivery room outcomes		1, 2, 3, 5, 8, 9, 10
Beyond delivery room outcomes		1, 2, 3, 6, 8, 9, 10
Long-term outcomes		1, 2, 3, 7, 8, 9, 10