

openMetaAnalysis: Risk of bias

Prognostic factor studies (*RCTs on next page of template*)

Table. Risk of bias for included studies. Based on the Cochrane's [QUIP](#) (PMID [23420236](#)) for prognostic factor studies.

Study	Subject selection	(Delete this yellow text box of instructions when done)				Confounding	Statistical Analysis and Reporting
Ball, 2014 PMID: 25056260	Low risk (all mothers in the time period included)	<ul style="list-style-type: none"> Enter assessment for each cell for the 7 domains (columns). For criteria, use the link in the header of the table. Fill cell color red if high risk and pink if unclear. Color the "Subjects and summary risk" column. If for a study, any domain (cell) is red, make the summary cell red. If none are red, but at least one is pink, make summary cell pink. 				Mothers tested	Low risk. Used conditional logistic regression to control for maternal factors
Hanley, 2017 PMID: 28178044	79	<ul style="list-style-type: none"> Add up the number of subjects from studies of low, unclear, and high risk and put the sums in the cell to the right of "Summary). If <ul style="list-style-type: none"> If > 50% of subjects from studies with high risk of bias, then color summary cell red for 'very serious risk of bias'. Else, if > 25% of subjects from studies with high risk of bias, color summary cell pink for 'Serious risk of bias'. 				Confounding included: age at time of delivery, diabetes, history of stillbirth	Low risk. Used conditional logistic regression to compare to same mother
Koullali, 2016 PMID: 27367283							
Schachar, 2016 PMID: 27405702							
Notes:							

* Assessment of individual studies based on the Cochrane Handbook, Table 8.5.d. Available at http://handbook.cochrane.org/chapter_8/table_8_5_d_criteria_for_judging_risk_of_bias_in_the_risk_of.htm.

† Summary determination across studies based on Cochrane Handbook, Table 8.7. Available at http://handbook.cochrane.org/chapter_8/table_8_7_a_possible_approach_for_summary_assessments_of_the.htm.

‡ Lack of a Consort diagram, by itself, is considered to be unclear risk for incomplete outcome and attrition bias.

§ Lack of trial registration, by itself, is considered to be unclear risk for selective reporting.

|| Method of randomization not clearly described.

¶ Method of blinding not clearly described.

Randomized controlled trials

Table. Risk of bias for included studies. Criteria for determinations are from the Cochrane Handbook, Table 8.5.d. Available at http://handbook-5-1.cochrane.org/chapter_8/table_8_5_d_criteria_for_judging_risk_of_bias_in_the_risk_of.htm.

Study	Subjects and summary risk*	Selection bias		Performance bias	Detection bias	Attrition bias	Reporting bias	Other biases
		Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	E.g. imbalanced compliance, co-interventions, or other.
Summary	Total: 6055 Low risk 20% Unclear risk: 22% High risk: 58%							
Svoboda, 2007 PMID: 17523274	72	Low risk	Low risk	Unclear risk	Unclear risk	Unclear risk	High risk	Low risk

Nobre, 2008 PMID: 18096708 NCT00250666	79	Low risk	Low risk	Unclear risk	Unclear risk	Low risk	Low risk	Low risk
Schroeder, 2009 PMID: 19034493	27	Unclear risk	Unclear risk	Unclear risk	Unclear risk	Low risk	High risk	Low risk
Hochreiter, 2009 PMID: 19493352 ISRCTN10288268	110	Unclear risk	Unclear risk	Low risk	Unclear risk	Low risk	Low risk	Low risk
ProGUARD, 2014 PMID: 25295709 ACTRN12610000809033	394	Low risk	Unclear risk	Unclear risk	Low risk	Low risk	Low risk	Low risk
Najafi, 2015 PMID: 26553084	60	Low risk	Unclear risk	High risk	Unclear risk	Unclear risk	High risk	Low risk
		Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	E.g. imbalanced compliance, co-interventions, or other.
		Random sequence generation		Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting

Notes:

* Summary determination based on Cochrane Handbook, Table 8.7. Available at http://handbook.cochrane.org/chapter_8/table_8_7_a_possible_approach_for_summary_assessments_of_the.htm

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