

Work sheet –Certainty of evidence (GRADE)

Disease/ disorder:
Intervention/ method vs. control:
Outcome variable: Preeclampsia
Included studies RCT, No..... SR, No..... Cohort studies, No.....
Number of patients:

Assessment of risk of bias (“internal validity”)

Assessment of “external validity” and precision

Study	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting	Other bias	Summary Risk of Bias

Directness	Precision

+ = low risk/good ? = unclear risk - = high risk/bad

Study limitations (Randomisation, blinding, follow-up, drop-out/withdrawals, intention-to-treat)	Mark with cross-sign
No serious limitations	
Some limitations (<i>but not enough to downgrade</i>)	
Serious limitations (<i>downgrade one step</i>)	
Very serious limitations (<i>downgrade two steps</i>)	
Comment limitations or reasons to downgrade:	
Consistency (Estimate of relative effect, same magnitude and direction across studies? overlapping confidence intervals?)	Mark with cross-sign
<input type="checkbox"/> Based on meta-analysis? Statistical analysis of heterogeneity: <input type="checkbox"/> Chi ² <input type="checkbox"/> I ²	
No serious inconsistency	
Some inconsistency (<i>but not enough to downgrade</i>)	
Serious inconsistency (<i>downgrade one step</i>)	
Very serious inconsistency (<i>downgrade two steps</i>)	
Comment limitations or reasons to downgrade:	

Directness (study population – external validity, specificity of intervention, relevance of the comparator to the intervention, clinical setting, adequate time of follow-up)	Mark with cross-sign	
No uncertainty		
Some uncertainty (<i>but not enough to downgrade</i>)		
Serious indirectness (<i>downgrade one step</i>)		
Very serious indirectness (<i>downgrade two steps</i>)		
Comment limitations or reasons to downgrade:		
Precision (Few events, wide confidence intervals that also include possible unfavourable effects)	Mark with cross-sign	
No imprecision		
Uncertain precision (<i>but not enough to downgrade</i>)		
Serious imprecision (<i>downgrade one step</i>)		
Very serious imprecision (<i>downgrade two steps</i>)		
Comment limitations or reasons to downgrade:		
Publication bias (Few and small studies from one research group or company which all show the same type of results, well.known unpublished studies)	Mark with cross-sign	
Unlikely		
Uncertainty (<i>but not enough to downgrade</i>)		
Likely (<i>downgrade one step</i>)		
Very likely (<i>downgrade two steps</i>)		
Comment limitations or reasons to downgrade:		
Magnitude of effect	Mark with cross-sign	
Not relevant		
Large effect (RR<0,5 or >2) (<i>upgrade one step</i>)		
Very large effect (RR<0,2 or >5) (<i>upgrade two steps</i>)		
Comment limitations or reasons to downgrade:		
Comments on other important aspects of the level of evidence (clear dose-response gradient that may allow upgrading (confounders that clearly reduce the magnitude of the effect)?		

Is the sum of uncertainties (?) enough to motivate downgrading with one step?	Mark with cross-sign	
Yes		
No		

Certainty of evidence	Mark with plus-signs	
High	⊕⊕⊕⊕	
Moderate	⊕⊕⊕○	
Low	⊕⊕○○	
Very low	⊕○○○	

Namn:

Datum:

Conclusion:
