Comparison 3: Opioids compared with placebo

Source: Deussen AR, Ashwood P, Martis R, Stewart F, LE G. Relief of pain due to uterine cramping/involution after birth. Cochrane Database Syst Rev. 2020;(10):CD004908.

Certainty assessment							№ of patients		Effect		Certainty (GRADE)	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Opioids	Placebo	Relative (95% CI)	Absolute (95% CI)		
Adequate pain relief as reported by the woman												
5	randomized trials	serious [a]	not serious	serious [b]	very serious [c,d]	none	89/165 (53.9%)	53/134 (39.6%)	**RR 1.26** (0.99 to 1.61)	**103 more per 1000** (from 4 fewer to 241 more)	⊕◯◯◯ VERY LOW	CRITICAL
Adequate pain relief as reported by the woman – codeine 60 mg vs placebo												
5	randomized trials	serious [a]	not serious	serious [b]	serious [d]	none	69/134 (51.5%)	43/118 (36.4%)	**RR 1.33** (1.01 to 1.76)	**120 more per 1000** (from 4 more to 277 more)	⊕◯◯◯ VERY LOW	CRITICAL
Adequate pain relief as reported by the woman – codeine 120 mg vs placebo												
1	randomized trials	serious [e]	not serious	serious [b]	very serious [c,d]	none	20/31 (64.5%)	10/16 (62.5%)	**RR 1.03** (0.65 to 1.64)	**19 more per 1000** (from 219 fewer to 400 more)	⊕◯◯◯ VERY LOW	CRITICAL
Need for additional pain relief												
3	randomized trials	serious [a]	not serious	serious [b]	serious [d]	none	19/170 (11.2%)	23/103 (22.3%)	**RR 0.48** (0.28 to 0.82)	**116 fewer per 1000** (from 161 fewer to 40 fewer)	⊕◯◯◯ VERY LOW	CRITICAL
Need for additional pain relief – codeine 60 mg vs placebo												
3	randomized trials	serious [a]	not serious	serious [b]	very serious [c,f]	none	10/104 (9.6%)	13/69 (18.8%)	**RR 0.49** (0.24 to 1.02)	**96 fewer per 1000** (from 143 fewer to 4 more)	⊕◯◯◯ VERY LOW	CRITICAL
Need for additional pain relief – codeine 120 mg vs placebo												
1	randomized trials	serious [e]	not serious	serious [b]	very serious [f]	none	1/31 (3.2%)	3/16 (18.8%)	**RR 0.17** (0.02 to 1.52)	**156 fewer per 1000** (from 184 fewer to 98 more)	⊕◯◯◯ VERY LOW	CRITICAL

Certainty assessment							№ of patients		Effect		Certainty (GRADE)	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Opioids	Placebo	Relative (95% CI)	Absolute (95% CI)		
Need for additional pain relief – nalbuphine 15 mg vs placebo												
1	randomized trials	serious [e]	not serious	serious [b]	very serious [c,f]	none	8/35 (22.9%)	7/18 (38.9%)	**RR 0.59** (0.25 to 1.36)	**159 fewer per 1000** (from 292 fewer to 140 more)	⊕◯◯◯ VERY LOW	CRITICAL
Maternal adverse effects												
3	randomized trials	serious [a]	not serious	serious [b]	very serious [c,d]	none	48/109 (44.0%)	21/79 (26.6%)	**RR 1.59** (0.99 to 2.55)	**157 more per 1000** (from 3 fewer to 412 more)	⊕◯◯◯ VERY LOW	CRITICAL
Maternal adverse effects – codeine 60 mg vs placebo												
3	randomized trials	serious [a]	not serious	serious [b]	very serious [c,d]	none	21/78 (26.9%)	18/63 (28.6%)	**RR 0.95** (0.54 to 1.67)	**14 fewer per 1000** (from 131 fewer to 191 more)	⊕◯◯◯ VERY LOW	CRITICAL
Maternal adverse effects – codeine 120 mg vs placebo												
1	randomized trials	serious [e]	not serious	serious [b]	very serious [d]	none	27/31 (87.1%)	3/16 (18.8%)	**RR 4.65** (1.66 to 13.00)	**684 more per 1000** (from 124 more to 1000 more)	⊕◯◯◯ VERY LOW	CRITICAL

CI: confidence interval; RR: risk ratio.
a. The pooled effect provided by studies "B".
b. Exclusion: breastfeeding women.
c. Wide confidence interval crossing the line of no effect.
d. Less than 300 women.
e. The pooled effect provided by study "B".
f. Less than 300 women and less than 30 events.