Comparison 1: Parenteral opioids compared with placebo or no opioids

Comparison 1.a. Pethidine intramuscular (IM) compared with placebo

Source:† Ullman R, Smith LA, Burns E, Mori R, Dowswell T. Parenteral opioids for maternal pain management in labour. Cochrane Database Syst Rev. 2010;(9):CD007396.

Quality assessment							No. of participants		Effect		Certainty (GRADE)	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pethidine IM	Placebo	Relative (95% CI)	Absolute (95% CI)		
Pain score (30 minutes post-analgesia)												
1	RCT	not serious	not serious	not serious	serious[a]	none	120	120	–	MD 4.1 lower (4.56 lower to 3.64 lower)	⨁⨁⨁◯ MODERATE	critical
Pain relief at 30 minutes (reduction in visual analogue scale of at least 40 mm)												
1	RCT	serious[b]	not serious	not serious	serious[c]	none	12/25 (48.0%)	0/25 (0.0%)	RR 25.00 (1.56–400.54)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁⨁◯◯ LOW	critical
Maternal satisfaction at 30 minutes (number of women "satisfied" or "very satisfied")												
1	RCT	serious[b]	not serious	not serious	very serious[d]	none	3/25 (12.0%)	0/25 (0.0%)	RR 7.00 (0.38–128.87)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⨁◯◯◯ VERY LOW	critical
Maternal pain relief "good" or "fair" (1 hour)												
1	RCT	serious[b]	not serious	not serious	serious[a]	none	42/58 (72.4%)	24/58 (41.4%)	RR 1.75 (1.24–2.47)	310 more per 1000 (from 99 more to 608 more)	⨁⨁◯◯ LOW	critical
Additional analgesia												
1	RCT	serious[b]	not serious	not serious	serious[a]	none	17/25 (68.0%)	24/25 (96.0%)	RR 0.71 (0.54–0.94)	278 fewer per 1000 (from 58 fewer to 442 fewer)	⨁⨁◯◯ LOW	critical
Epidural												
1	RCT	serious[b]	not serious	not serious	very serious[d]	none	3/25 (12.0%)	6/25 (24.0%)	RR 0.50 (0.14–1.78)	120 fewer per 1000 (from 187 more to 206 fewer)	⨁◯◯◯ VERY LOW	critical

† Updated for the purpose of this guideline.

Quality assessment							No. of participants		Effect		Certainty (GRADE)	Importance
No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Pethidine IM	Placebo	Relative (95% CI)	Absolute (95% CI)		
Assisted vaginal delivery												
2	RCTs	serious[b]	not serious	not serious	very serious[e]	none	15/145 (10.3%)	19/145 (13.1%)	RR 0.79 (0.42–1.47)	28 fewer per 1000 (from 62 more to 76 fewer)	⨁◯◯◯ VERY LOW	critical
Caesarean section												
3	RCTs	serious[b]	not serious	not serious	serious[f]	none	27/190 (14.2%)	34/190 (17.9%)	RR 0.79 (0.50–1.26)	38 fewer per 1000 (from 47 more to 89 fewer)	⨁⨁◯◯ LOW	critical
Nausea and vomiting												
3	RCTs	serious[b]	not serious	not serious	not serious	none	29/203 (14.3%)	15/203 (7.4%)	RR 1.90 (1.06–3.40)	67 more per 1000 (from 4 more to 177 more)	⨁⨁⨁◯ MODERATE	critical
Maternal sleepiness												
2	RCTs	serious[b]	not serious	not serious	seriousa	none	42/83 (50.6%)	9/83 (10.8%)	RR 4.67 (2.43–8.95)	398 more per 1000 (from 155 more to 862 more)	⨁⨁◯◯ LOW	critical
Low Apgar score (≤ 7) at 5 minutes												
2	RCTs	serious[b]	very serious[g]	not serious	serious[f]	none	0/100 (0.0%)	0/100 (0.0%)	not pooled	not estimable	–	critical
Neonatal resuscitation												
1	RCT	serious[b]	not serious	not serious	very serious[d]	none	5/25 (20.0%)	3/25 (12.0%)	RR 1.67 (0.45–6.24)	80 more per 1000 (from 66 fewer to 629 more)	⨁◯◯◯ VERY LOW	critical

CI: confidence interval; MD: mean difference; RCT: randomized controlled trial; RR: risk ratio.

[a] Small sample size.

[b] Effect estimate derived from a single study with a moderate risk of bias.

[c] Small sample size and few events.

[d] Wide confidence interval crossing the line of no effect, few events and small sample size.

[e] Wide confidence interval crossing the line of no effect and small sample size.

[f] Wide confidence interval crossing the line of no effect.

[g] Severe unexplained heterogeneity.