Comparison 2.g. Nalbuphine intramuscular (IM) compared with pethidine (IM)

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.

No. of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nalbuphine IM	Pethidine IM	Relative (95% CI)	Absolute (95% CI)	Certainty (GRADE)	Importance
Quality assessment							**No. of participants**		**Effect**			
Maternal satisfaction with analgesia at 24 hours – numbers dissatisfied												
1	RCT	serious[a]	not serious	not serious	serious[b]	none	23/37 (62.2%)	30/35 (85.7%)	RR 0.73 (0.55–0.96)	231 fewer per 1000 (from 34 fewer to 386 fewer)	⊕⊕◯◯ LOW	critical
Pain free												
1	RCT	serious[c]	not serious	not serious	very serious[d]	none	6/20 (30.0%)	1/20 (5.0%)	RR 6.00 (0.79–45.42)	250 more per 1000 (from 10 fewer to 1000 more)	⊕◯◯◯ VERY LOW	critical
Pain intensity at 30 minutes – women with severe pain												
1	RCT	serious[a]	not serious	not serious	very serious[e]	none	37/149 (24.8%)	42/146 (28.8%)	RR 0.86 (0.59–1.26)	40 fewer per 1000 (from 75 more to 118 fewer)	⊕◯◯◯ VERY LOW	critical
Visual analogue score at 60 minutes (at peak of contraction)												
1	RCT	serious[a]	not serious	not serious	very serious[e]	none	37	35	–	MD 8 lower (18.55 lower to 2.55 higher)	⊕◯◯◯ VERY LOW	critical
Additional analgesia needed												
1	RCT	serious[a]	not serious	not serious	very serious[d]	none	8/37 (21.6%)	6/35 (17.1%)	RR 1.26 (0.49–3.27)	45 more per 1000 (from 87 fewer to 389 more)	⊕◯◯◯ VERY LOW	critical
Epidural												
1	RCT	not serious	not serious	not serious	very serious[f]	none	8/151 (5.3%)	5/156 (3.2%)	RR 1.65 (0.55–4.94)	21 more per 1000 (from 14 fewer to 126 more)	⊕⊕◯◯ LOW	critical
Nausea and vomiting – nausea and vomiting												
1	RCT	serious[g]	not serious	not serious	not serious	none	6/37 (16.2%)	14/35 (40.0%)	RR 0.41 (0.18–0.94)	236 fewer per 1000 (from 24 fewer to 328 fewer)	⊕⊕⊕◯ MODERATE	critical

† Updated for the purpose of this guideline.

No. of studies	Study design	Quality assessment					No. of participants		Effect		Certainty (GRADE)	Importance
		Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Nalbuphine IM	Pethidine IM	Relative (95% CI)	Absolute (95% CI)		
Maternal sleepiness												
1	RCT	serious[a]	not serious	not serious	very serious[d]	none	8/37 (21.6%)	2/35 (5.7%)	RR 3.78 (0.86–16.60)	159 more per 1000 (from 8 fewer to 891 more)	⊕◯◯◯ VERY LOW	critical
Assisted vaginal delivery												
2	RCTs	serious[g]	not serious	not serious	very serious[f]	none	14/189 (7.4%)	12/193 (6.2%)	RR 0.98 (0.25–3.85)	1 fewer per 1000 (from 47 fewer to 177 more)	⊕◯◯◯ VERY LOW	critical
Caesarean section												
1	RCT	not serious	not serious	not serious	very serious[f]	none	3/152 (2.0%)	7/158 (4.4%)	RR 0.45 (0.12–1.69)	24 fewer per 1000 (from 31 more to 39 fewer)	⊕⊕◯◯ LOW	critical
Low Apgar score (≤ 7) at 1 and 5 minutes – low score at 5 minutes												
1	RCT	serious[a]	not serious	not serious	very serious[d]	none	1/37 (2.7%)	2/35 (5.7%)	RR 0.47 (0.04–4.99)	30 fewer per 1000 (from 55 fewer to 228 more)	⊕◯◯◯ VERY LOW	critical
Naloxone administration (neonatal)												
1	RCT	serious[a]	not serious	not serious	very serious[d]	none	3/37 (8.1%)	0/35 (0.0%)	RR 6.63 (0.35–123.93)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⊕◯◯◯ VERY LOW	critical
Neonatal neurobehavioural score (Scanlon) (measured 2–4 hours after birth)												
1	RCT	serious[a]	not serious	not serious	serious[b]	none	37	35	–	MD 3.7 lower (6.14 lower to 1.26 lower)	⊕⊕◯◯ LOW	critical

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

[a] Effect estimate from single study with a moderate risk of bias.
[b] Small sample size.
[c] Effect estimate from single study with a high risk of bias.
[d] Wide confidence interval crossing the line of no effect, small sample size and few events.
[e] Wide confidence interval crossing the line of no effect and small sample size.
[f] Wide confidence interval crossing the line of no effect and few events.
[g] Pooled effect derived from studies with a moderate risk of bias.