Comparison 2: Perineal local cooling compared with other forms of non-pharmacological interventions

Comparison 2a: Perineal cooling and compression compared with uncooled gel pads and compression after vaginal birth in women with non-severe perineal trauma

Source: East CE, Dorward EDF, Whale RE, Liu J. Local cooling for relieving pain from perineal trauma sustained during childbirth. Cochrane Database Syst Rev. 2020;(10):CD006304.

			Certainty asse	essment			Nº of p	atients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cooling treatment (cold gel pad) + compression	Uncooled gel pad + compression	Relative (95% Cl)	Absolute (95% CI)	Certainty (GRADE)	Importance

Perineal pain within 4–6 hours of birth

1	randomized not trials seriou	not serious	serious ^a	very serious ^{b,c}	none	125	125	-	MD 0.32 lower (0.78 lower to 0.14 higher)	⊕○○○ VERY LOW	IMPORTANT
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Perineal pain within 24–48 hours after birth

1	randomized	not	not serious	serious ^a	serious ^c	none	125	125	-	MD 0.43 lower	$\oplus \oplus \bigcirc \bigcirc$	IMPORTANT
	trials	serious								(0.73 lower to 0.13 lower)	LOW	

Perineal oedema 24–48 hours after birth

1	randomized trials	not serious	not serious	serious ^a	serious ^c	none	125	125	-	MD 0.15 lower (0.28 lower to 0.03 lower)	⊕⊕⊖⊖ Low	IMPORTANT	
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Perineal bruising 24–48 hours after birth

1	randomized trials	not serious	not serious	serious ^a	very serious ^{c,d}	none	125	125	-	MD 0 (0 to 0)	⊕⊖⊖⊖ VERY LOW	IMPORTANT	
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Satisfaction with perineal care

1	randomized trials	not serious	not serious	serious ^a	serious ^c	none	125	125	-	MD 0.88 higher (0.38 higher to 1.38 higher)		IMPORTANT	
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CI: confidence interval; MD: mean difference.

a. Intervention was mainly focused on prevention and not relief of pain.

b. Wide confidence interval crossing the line of no effect.

c. Less than 400 participants.

d. No events.

Comparison 2b: Perineal cooling (ice packs) compared with room temperature water packs after vaginal birth in women with non-severe perineal trauma

Source: East CE, Dorward EDF, Whale RE, Liu J. Local cooling for relieving pain from perineal trauma sustained during childbirth. Cochrane Database Syst Rev. 2020;(10):CD006304.

			Certainty asses	sment			Nº of ∣	patients	l	ffect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cooling treatment (ice pack)	Room temperature water pack	Relative (95% Cl)	Absolute (95% Cl)	Certainty (GRADE)	Importance
Perineal	pain within 4–0	6 hours after b	irth									
1	randomized trials	not serious	not serious	serious ^a	very serious ^{b,c}	none	0/28 (0.0%)	0/35 (0.0%)	not estimable	-	⊕○○○ VERY LOW	IMPORTANT
Perineal	pain within 24	hours after bir	rth	<u>!</u>		ļ						
1	randomized trials	not serious	not serious	serious ^a	very serious ^{b,c}	none	0/28 (0.0%)	0/35 (0.0%)	not estimable	-	⊕○○○ VERY LOW	IMPORTANT
Perineal	oedema within	n 4–6 hours aft	er birth	•				•				
1	randomized trials	not serious	not serious	serious ^a	very serious ^{c,d,e}	none	10/28 (35.7%)	13/35 (37.1%)	RR 0.96 (0.50 to 1.86)	15 fewer per 1000 (from 186 fewer to 319 more)	⊕○○○ VERY LOW	IMPORTANT
Perineal	oedema within	a 24 hours afte	r birth									·
1	randomized trials	not serious	not serious	serious ^a	very serious ^{c,d,e}	none	2/28 (7.1%)	7/35 (20.0%)	RR 0.36 (0.08 to 1.59)	128 fewer per 1000 (from 184 fewer to 118 more)	⊕○○○ VERY LOW	IMPORTANT
Addition	al analgesia foi	r relief of perin	eal pain within	24 hours after	birth	I		1				
1	randomized trials	not serious	not serious	serious ^a	very serious ^{c,d}	none	10/28 (35.7%)	20/35 (57.1%)	RR 0.63 (0.35 to 1.11)	211 fewer per 1000 (from 371 fewer to 63 more)	⊕○○○ VERY LOW	IMPORTANT
Materna	I exhaustion w	ithin 4–6 hours	s after birth			<u>.</u>						••
1	randomized trials	not serious	not serious	serious ^a	very serious ^{b,c}	none	0/28 (0.0%)	0/35 (0.0%)	not estimable	-	⊕○○○ VERY LOW	IMPORTANT
Materna	I exhaustion w	ithin 24 hours	after birth	·	·	·		·				<u> </u>
1	randomized trials	not serious	not serious	serious ^a	very serious ^{b,c}	none	0/28 (0.0%)	0/35 (0.0%)	not estimable	-	⊕⊖⊖⊖ VERY LOW	IMPORTANT

			Certainty asses	sment			Nº of p	oatients	I	Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cooling treatment (ice pack)	Room temperature water pack	Relative (95% Cl)	Absolute (95% Cl)	Certainty (GRADE)	Importance

Maternal views and experiences with treatment – satisfied with treatment

1	randomized trials	not serious	not serious	serious ^a	serious ^c	none	24/28 (85.7%)	33/35 (94.3%)	RR 0.91 (0.77 to 1.08)	85 fewer per 1000 (from 217 fewer to	IMPORTANT
										75 more)	

Maternal views and experiences with treatment - would repeat treatment in future childbirth

1	randomized trials	not serious	not serious	serious ^a	serious ^c	none	24/28 (85.7%)	34/35 (97.1%)	RR 0.88 (0.75 to 1.04)	117 fewer per 1000 (from 243 fewer to 39 more)		IMPORTANT	
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Maternal views and experiences with treatment – would recommend treatment

1	randomized trials	not serious	not serious	serious ^a	serious ^c	none	25/28 (89.3%)	35/35 (100.0%)	RR 0.89 (0.77 to 1.03)	110 fewer per 1000 (from 230 fewer to 30 more)	⊕⊕⊖⊖ Low	IMPORTANT
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Women providing any breastmilk to the baby 48 hours after birth

1	randomized trials	not serious	not serious	serious ^a	serious ^c	none	28/28 (100.0%)	35/35 (100.0%)	RR 1.00 (0.94 to 1.06)	0 fewer per 1000 (from 60 fewer to 60 more)	⊕⊕⊖⊖ Low	IMPORTANT
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CI: confidence interval; RR: risk ratio.

a. Intervention was mainly focused on prevention and not relief of pain.

b. No events.

c. Less than 300 participants.

d. Wide confidence interval crossing the line of no effect.

e. Less than 30 events.

Comparison 2c: Perineal cooling (ice packs) compared with cold gel pads after vaginal birth in women with non-severe perineal trauma

Source: East CE, Dorward EDF, Whale RE, Liu J. Local cooling for relieving pain from perineal trauma sustained during childbirth. Cochrane Database Syst Rev. 2020;(10):CD006304.

			Certainty asses	sment			Nº of	patients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cooling treatment (ice pack)	Cooling treatment (cold gel pad)	Relative (95% Cl)	Absolute (95% Cl)	Certainty (GRADE)	Importance
Perineal	pain within 4–	6 hours after b	irth – moderate	+ severe pain								
1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	6/22 (27.3%)	13/27 (48.1%)	RR 0.57 (0.26 to 1.24)	207 fewer per 1000 (from 356 fewer to	⊕○○○ VERY LOW	IMPORTANT

Perineal pain within 24 hours of birth – moderate + severe pain

	ewer per 1000 a 119 fewer to VERY LOW IMPORT 119 more)	ANT
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116 more)

Perineal pain within 24 hours of birth

1 randomized trials serious a serious a not serious b serious b higher serious b serious c,e none 35 39 - MD 0.58 higher (0.44 lower to 1.6 higher) $\oplus \bigcirc \bigcirc$
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Perineal pain 24–48 hours after birth – moderate + severe pain

2	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	54/129 (41.9%)	46/134 (34.3%)	RR 1.21 (0.89 to 1.65)	72 more per 1000 (from 38 fewer to 223 more)	⊕○○○ VERY LOW	IMPORTANT	
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Perineal pain 24–48 hours after birth

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,e}	none	35	39	-	MD 0.86 higher (0.1 lower to 1.82 higher)	⊕○○○ VERY LOW	IMPORTANT
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Perineal oedema within 4–6 hours after birth

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	17/22 (77.3%)	15/27 (55.6%)	RR 1.39 (0.93 to 2.09)	217 more per 1000 (from 39 fewer to 606 more)	⊕○○○ VERY LOW	IMPORTANT

			Certainty asses	sment			Nº of	patients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cooling treatment (ice pack)	Cooling treatment (cold gel pad)	Relative (95% CI)	Absolute (95% Cl)	Certainty (GRADE)	Importance

Perineal oedema within 24 hours after birth

2	randomized trials	serious ^a	not serious	serious ^b	serious ^d	none	92/129 (71.3%)	99/135 (73.3%)	RR 0.97 (0.84 to 1.13)	22 fewer per 1000 (from 117 fewer to 95 more)	⊕○○○ VERY LOW	IMPORTANT
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Perineal oedema 24–48 hours after birth

more)		2	randomized trials	serious ^a	not serious	serious ^b	serious ^d	none	79/129 (61.2%)	53/135 (39.3%)	RR 1.69 (1.03 to 2.77)	271 more per 1000 (from 12 more to 695 more)	⊕○○○ VERY LOW	IMPORTANT
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Perineal bruising within 4–6 hours of birth

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	7/22 (31.8%)	7/27 (25.9%)	RR 1.23 (0.51 to 2.97)	60 more per 1000 (from 127 fewer to 511 more)	⊕⊖⊖⊖ VERY LOW	IMPORTANT
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Perineal bruising within 24 hours of birth

2	randomized trials	serious ^a	not serious	serious ^b	serious ^d	none	78/129 (60.5%)	87/135 (64.4%)	RR 0.95 (0.79 to 1.14)	32 fewer per 1000 (from 135 fewer to 90 more)	⊕○○○ VERY LOW	IMPORTANT	
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Perineal bruising 24–48 hours of birth

2 randomized serious ^a trials	not serious serious b	serious ^d	none	96/129 (74.4%)	94/135 (69.6%)	RR 1.07 (0.92 to 1.25)	49 more per 1000 (from 56 fewer to 174 more)	⊕○○○ VERY LOW	IMPORTANT
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Perineal redness, oedema, bruising, discharge, wound gaping within 24 hours of birth

1	randomized trials	serious ^a	not serious	serious ^b	serious ^e	none	35	39	-	MD 0.13 lower (0.85 lower to 0.59 higher)	⊕⊖⊖⊖ VERY LOW	IMPORTANT

Perineal redness, oedema, bruising, discharge, wound gaping 24-48 hours after birth

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,e}	none	35	39	-	MD 0.2 higher (0.33 lower to 0.73 higher)	⊕○○○ VERY LOW	IMPORTANT	
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			Certainty asses	sment			Nº of	patients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cooling treatment (ice pack)	Cooling treatment (cold gel pad)	Relative (95% CI)	Absolute (95% Cl)	Certainty (GRADE)	Importance

Additional analgesia for relief of perineal pain: within 24 hours of birth - non-prescription analgesia

142 more)		1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	29/107 (27.1%)	30/108 (27.8%)	RR 0.98 (0.63 to 1.51)	6 fewer per 1000 (from 103 fewer to 142 more)	⊕⊖⊖⊖ VERY LOW	IMPORTANT
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Additional analgesia for relief of perineal pain: within 24 hours of birth - prescription analgesia

Additional analgesia for relief of perineal pain: 24–48 hours after birth – non-prescription analgesia

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	27/107 (25.2%)	24/108 (22.2%)	RR 1.14 (0.70 to 1.84)	31 more per 1000 (from 67 fewer to 187 more)	⊕○○○ VERY LOW	IMPORTANT	
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Additional analgesia for relief of perineal pain: 24-48 hours after birth - prescription analgesia

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	24/107 (22.4%)	36/108 (33.3%)	RR 0.67 (0.43 to 1.05)	110 fewer per 1000 (from 190 fewer to 17 more)	⊕○○○ VERY LOW	IMPORTANT	
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Pain associated with activities of daily living (sitting) within 24 hours of birth

1	randomized so trials	serious ^a	not serious	serious ^b	serious ^d	none	101/105 (96.2%)	105/107 (98.1%)	RR 0.98 (0.94 to 1.03)	20 fewer per 1000 (from 59 fewer to 29 more)	⊕○○○ VERY LOW	IMPORTANT	
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Pain associated with activities of daily living (sitting) 24-48 hours after birth

1	randomized trials	serious ^a	not serious	serious ^b	serious ^d	none	99/105 (94.3%)	104/107 (97.2%)	RR 0.97 (0.92 to 1.03)	29 fewer per 1000 (from 78 fewer to 29 more)	⊕⊖⊖⊖ VERY LOW	IMPORTANT	
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Pain associated with activities of daily living (walking) within 24 hours of birth

1	randomized trials	serious ^a	not serious	serious ^b	serious ^d	none	95/105 (90.5%)	101/107 (94.4%)	RR 0.96 (0.89 to 1.04)	38 fewer per 1000 (from 104 fewer to 38 more)	⊕○○○ VERY LOW	IMPORTANT	
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			Certainty asses	sment			Nº of	patients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cooling treatment (ice pack)	Cooling treatment (cold gel pad)	Relative (95% CI)	Absolute (95% Cl)	Certainty (GRADE)	Importance

Pain associated with activities of daily living (walking) 24-48 hours of birth

1 randomized serious ^a not serious serious ^b serious ^d none 91/105 99/107 RR 0.94 56 fewer per 1000 ⊕○○○ trials trials a a b a a a a a a b b a b b a b b a b	1		not serious serious ^b	serious ^d no		99/107 (92.5%)	RR 0.94 (0.85 to 1.03)	•	⊕○○○ VERY LOW	IMPORTANT
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Pain associated with activities of daily living (feeding baby) within 24 hours of birth

120 more)

Pain associated with activities of daily living (feeding baby) 24-48 hours after birth

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	34/104 (32.7%)	32/107 (29.9%)	RR 1.09 (0.73 to 1.63)	27 more per 1000 (from 81 fewer to 188 more)	⊕○○○ VERY LOW	IMPORTANT	
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Maternal views and experiences with treatment at day 5 - opinion on treatment effects (good + very good + excellent)

1	randomized trials	serious ^a	not serious	serious ^b	serious ^f	none	6/22 (27.3%)	22/27 (81.5%)	RR 0.33 (0.17 to 0.68)	546 fewer per 1000 (from 676 fewer to 261 fewer)	⊕○○○ VERY LOW	IMPORTANT	
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Maternal views and experiences with treatment at day 10 satisfaction with overall perineal care (good + very good + excellent)

trials (76.5%) (93.4%) (0.73 to 0.92) (from 252 fewer to 75 VERY LOW fewer) fewer) (76.5%) (93.4%) (0.73 to 0.92) (from 252 fewer to 75 VERY LOW	1	randomized trials	serious ^a	not serious	serious ^b	serious ^d	none	78/102 (76.5%)	99/106 (93.4%)	RR 0.82 (0.73 to 0.92)	168 fewer per 1000 (from 252 fewer to 75 fewer)	⊕⊖⊖⊖ VERY LOW	IMPORTANT
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Women providing any breastmilk to the baby 48 hours after birth

1	randomized trials	serious ^a	not serious	serious ^b	very serious ^{c,d}	none	62/105 (59.0%)	60/107 (56.1%)	RR 1.05 (0.84 to 1.33)	28 more per 1000 (from 90 fewer to 185 more)	⊕○○○ VERY LOW	IMPORTANT	
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CI: confidence interval; MD: mean difference; RR: risk ratio.

a. The pooled effect provided by study "B".

b. Intervention is mainly focused on prevention and not relief of pain.

c. Wide confidence interval crossing the line of no effect.

d. Less than 300 participants.

e. Less than 400 participants.

f. Less than 300 women and less than 30 events.