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Date: 2015-03-06

Question: Should a combined holding intervention post-injection vs control be used for reducing vaccine injection pain in children in the first 3 years of life?

Settings: hospital or clinic

Bibliography: Chou 2012, Harrington 2012 (1,2)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	A combined holding intervention post-injection	Control	Relative (95% CI)	Absolute		
Distress Acute ¹ (measured with: validated tools (Visual Analog Scale 0-100, Neonatal Facial Coding Scale 0-9) by researcher; Better indicated by lower values)												
1	randomised trials ¹	serious ²	no serious inconsistency	no serious indirectness	serious ³	none	88	99	-	SMD 0.37 lower (0.66 to 0.08 lower) ¹	⊕⊕○○ LOW	CRITICAL
Distress Acute + Recovery ¹ (measured with: validated tools (Modified Riley Scale 0-9, Measure of Adult Infant Soothing Distress 0-1) by researcher; Better indicated by lower values)												
2	randomised trials ¹	very serious ^{2,4}	no serious inconsistency ⁵	no serious indirectness	no serious imprecision	none	204	213	-	SMD 0.65 lower (1.08 to 0.22 lower) ¹	⊕⊕○○ LOW	CRITICAL
Procedure Outcomes, Parent Fear, Use of Intervention, Vaccine Compliance, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

¹ In 1 study (Chou 2012), 149 infants participated; however, 38 participated twice. The data are treated as independent

² Immunizers and outcome assessors not blinded

³ Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

⁴ In 1 study (Harrington 2012), the holding intervention included swaddling which may have interfered with pain assessment as infant movements may not have been visible; oral rotavirus vaccine was administered prior to procedure.

⁵ Heterogeneity may be explained by differences in the interventions; in 1 study (Chou 2012), nurse holding the infant upright against the chest and back patting was compared to lying supine. In Harrington 2012 (1), 5S (swaddling, side-lying, shushing, swinging, sucking) carried out by a pediatric resident was compared to usual care by parent. In Harrington 2012 (2), 5S and sucrose was compared to sucrose.