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Question: Should acetaminophen vs placebo be used for reducing vaccine injection pain in people of all ages?

Settings: hospital

Bibliography: Aoki 1993, Chernesky 1993, Doedee 2014, Gross 1994, Heden 2014. Prymula 2009

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acetaminophen	Placebo	Relative (95% CI)	Absolute		
Pain (measured with: validated tool (Visual Analog Scale, 0-100); Better indicated by lower values)												
1	randomised trials ¹	no serious risk of bias	no serious inconsistency	serious ²	serious ³	none	12	14	-	SMD 0.64 lower (1.43 lower to 0.15 higher)	⊕⊕○○ LOW	CRITICAL
Fear (measured with: validated tool (Visual Analog Scale 0-100); Better indicated by lower values)												
1	randomised trials ¹	no serious risk of bias	no serious inconsistency	serious ²	serious ³	none	12	14	-	SMD 0.68 lower (1.48 lower to 0.12 higher)	⊕⊕○○ LOW	IMPORTANT
Distress (measured with: validated tool (Children's Hospital of Eastern Ontario Pain Scale 4-13, Visual Analog Scale 0-100) by nurses, researcher, parent; Better indicated by lower values)												
1	randomised trials ¹	no serious risk of bias	no serious inconsistency	serious ²	serious ³	none	24	27	-	SMD 0.13 lower (0.68 lower to 0.42 higher)	⊕⊕○○ LOW	IMPORTANT ⁴
Safety ⁵ (measured with: validated tool (antibody titres, proportion of individuals with adequate antibody titres); Better indicated by lower values)												
5	randomised trials					none	0	-	- ⁵	not pooled ⁵		IMPORTANT
Vaccine Compliance, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence					none	-	-	-	-		IMPORTANT

	available							0%		-		
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¹ Children in both groups received topical anesthetics and children in the intervention group (acetaminophen) received 40mg/kg.

² Study (Heden 2014) includes children with cancer undergoing needle insertion into a subcutaneously implanted port.

³ Confidence interval crosses the line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

⁴ In included study (Heden 2014), 26/51 children were included in this analysis who were able to self-report pain; hence, this outcome was downgraded to an important outcome

⁵ In 5 included studies (Aoki 1993, Chernesky 1993, Gross 1994, Doedee 2014, Prymula 2009), 3 did not demonstrate an effect and 2 demonstrated a reduction in selected antibody titre levels in the acetaminophen group compared to control. A variety of vaccines and acetaminophen dosing regimens were evaluated in these studies.