

Table 63: Clinical evidence profile: Comparison 1.2. PERT + Ranitidine versus. PERT alone in children

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	PERT + Ranitidine	PERT alone	Relative (95% CI)	Absolute		
Fat absorption (CFA) (follow-up 12 days; measured as: % of intake, or consumed fat that is absorbed; Better indicated by higher values) [PERT + low-dose ranitidine]												
1 (Francisco 2002) ²	randomised trials ¹	no serious risk of bias	no serious inconsistency	no serious indirectness	Not calculable ³	none ⁴	12 Median: 83.60 (74.10 to 89.67) versus. 80.37 (72.43 to 89.44)	-		p=0.87*	HIGH	CRITICAL
Fat absorption (CFA) (follow-up 12 days; measured as: % of intake, or consumed fat that is absorbed; Better indicated by higher values) [PERT + high-dose ranitidine]												
1 (Francisco 2002) ⁵	randomised trials ¹	no serious risk of bias	no serious inconsistency	no serious indirectness	Not calculable ³	none ⁴	12 Median 80.91 (74.15 to 88.21) versus. 80.37 (72.43 to 89.44)	-		p=1*	HIGH	CRITICAL

Abbreviations: CFA: coefficient of fat absorption; CI: confidence interval; MD: mean difference; PERT: pancreatic endocrine enzyme therapy

* The paper provided raw data. Medians and p-values were calculated by the NGA technical team

1 Cross-over trial

2 Treatment details: low-dose Pancrease M10 or M16 + ranitidine or placebo. Children weighting ≤40 kg were given 5 mg/kg. Children weighting >40 kg received 150 mg. twice daily.

3 Imprecision cannot be calculated from medians.

4 Reporting bias not detected, but drugs were provided by the Pharmaceutical industry

5 Treatment details: high-dose Pancrease M10 or M16 + ranitidine or placebo. Children weighting ≤40 kg were given 10 mg/kg. Children weighting >40 kg received 300 mg. twice daily.