

Comparison: Vitamin D supplementation for breastfed, term infants compared with placebo or no supplementation

Source: Tan ML, Abrams SA, Osborn DA. Vitamin D supplementation for term breastfed infants to prevent vitamin D deficiency and improve bone health. Cochrane Database Syst Rev. 2020;(12):CD013046.

Certainty assessment							No of patients		Effect		Certainty (GRADE)	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vitamin D	Placebo or no supplementation	Relative (95% CI)	Absolute (95% CI)		
Vitamin D insufficiency (25(OH) vitamin D < 50 nmol/L)												
4	randomized trials	serious ^a	not serious	not serious	serious ^b	none	29/132 (22.0%)	64/142 (45.1%)	RR 0.57 (0.41 to 0.80)	194 fewer per 1000 (from 266 fewer to 90 fewer)	⊕⊕○○ LOW	CRITICAL
Serum 25(OH) vitamin D level at latest time reported to 6 months of age												
6	randomized trials	serious ^a	not serious	not serious	serious ^c	none	159	175	-	MD 22.63 higher (17.05 higher to 28.21 higher)	⊕⊕○○ LOW	CRITICAL
Vitamin D deficiency (25(OH) vitamin D < 30 nmol/L)												
2	randomized trials	serious ^d	not serious	not serious	very serious ^{e,g}	none	5/58 (8.6%)	14/64 (21.9%)	RR 0.41 (0.16 to 1.05)	129 fewer per 1000 (from 184 fewer to 11 more)	⊕○○○ VERY LOW	CRITICAL
Nutritional rickets – biochemical												
2	randomized trials	serious ^d	not serious	not serious	very serious ^{b,h}	none	0/17 (0.0%)	0/17 (0.0%)	not estimable	not estimable	⊕○○○ VERY LOW	CRITICAL
Size at latest time measured – weight												
2	randomized trials	serious ^d	not serious	not serious	very serious ^e	none	71	72	-	MD 123.63 higher (170.02 lower to 417.28 higher)	⊕○○○ VERY LOW	CRITICAL
Size at latest time measured – length												
3	randomized trials	serious ^d	not serious	not serious	very serious ^{d,e}	none	77	79	-	MD 0.73 higher (0.11 lower to 1.57 higher)	⊕○○○ VERY LOW	CRITICAL
Size at latest time measured – head circumference at 6 months of age												
1	randomized trials	serious ^d	not serious	not serious	very serious ^{d,e}	none	52	53	-	MD 0 (0.6 lower to 0.6 higher)	⊕○○○ VERY LOW	CRITICAL

Certainty assessment							No of patients		Effect		Certainty (GRADE)	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Vitamin D	Placebo or no supplementation	Relative (95% CI)	Absolute (95% CI)		
Bone mineral content at the end of intervention												
2	randomized trials	serious ^d	serious ^f	not serious	very serious ^{c,e}	none	28	28	-	MD 3.93 higher (2.42 lower to 10.27 higher)	⊕○○○ VERY LOW	CRITICAL
Adverse effect – hypercalcaemia												
1	randomized trials	serious ^d	not serious	not serious	very serious ^{e,g}	none	8/47 (17.0%)	6/51 (11.8%)	RR 1.45 (0.54 to 3.86)	53 more per 1000 (from 54 fewer to 336 more)	⊕○○○ VERY LOW	CRITICAL
Adverse effect – others												
3	randomized trials	very serious ⁱ	not serious	not serious	very serious ^{e,g}	none	1/25 (4.0%)	0/24 (0.0%)	RR 3.00 (0.14 to 64.26)	0 fewer per 1000 (from 0 fewer to 0 fewer)	⊕○○○ VERY LOW	CRITICAL

CI: confidence interval; MD: mean difference; RR: risk ratio.

- a. Most of the pooled effect provided by studies “B”.
- b. Less than 300 babies.
- c. Less than 400 babies.
- d. The effect provided by studies “B”.
- e. Wide confidence interval crossing the line of no effect.
- f. Statistical heterogeneity (I^2 94%).
- g. Less than 300 participants and less than 30 events.
- h. No events.
- i. Most of the pooled effect provided by study “C”.