

Summary of findings:





11 Zinc supplementation compared to placebo for prevention of acute otitis media

Patient or population: Children aged 0-31 months.

Setting: Primary health care.

Intervention: Zinc supplementation. (Studies used: 10-20mg elemental zinc daily) Duration was for 4-6 months.

Comparison: Placebo.

Outcome № of participants (studies)	Relative effect (95% CI)	Anticipated absolute effects (95% CI)			Quality	What happens
		Without Zinc supplementation	With Zinc supplementation	Difference		
Any AOM assessed with: otoscope +/- otorrhoea follow up: range 4 to 6 months № of participants: 3191 (2 RCTs) ^{1,a}	RR 1.05 (0.82 to 1.36)	6.8%	7.2% (5.6 to 9.3)	0.3% more (NS) (1.2 fewer to 2.5 more)	 MODERATE ^{b,c}	In children receiving zinc supplements compared to placebo there is probably no reduction in AOM during 4-6 months follow up. NNT Not Applicable
>1 episode of definite otitis media assessed with: physician diagnosed AOM follow up: median 4 months № of participants: 2482 (1 RCT) ^{1,d}	RR 1.08 (0.50 to 2.36)	1.0%	1.0% (0.5 to 2.3)	0.1% more(NS) (0.5 fewer to 1.3 more)	 MODERATE ^{b,c}	In children receiving zinc supplements compared to placebo there is probably no difference in recurrent AOM episodes during 4-6 months follow up. NNT Not Applicable
Adverse events - discontinued supplement due to vomiting assessed with: parental report follow up: median 4 months № of participants: 2482 (1 RCT) ^{1,d}	RR 17.00 (0.98 to 294.21)	0.0%	0.6% (0.0 to 0.0)	0.6% fewer (NS) (0 fewer to 0 fewer)	 LOW ^{b,c}	In children treated with zinc supplements compared to placebo for prevention of AOM there are possibly more adverse effects (vomiting) which have lead to discontinuation of treatment. NNT Not Applicable
Adverse events - Days with vomiting during intervention (per child for period of follow-up) assessed with: parental report follow up: median 4 months № of participants: 2482 (1 RCT) ^{1,d}	-	The mean days with vomiting during intervention (per child for period of follow-up) was 2.6 days	-	MD 1.7 days higher (1.31 higher to 2.09 higher)	 LOW ^{b,e}	Children receiving zinc supplements compared to placebo for prevention of AOM possibly experience more mean days with vomiting during 4 months follow up.

*The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; RR: Risk ratio; NS: Not significant; NNT: Number needed to treat; NNH: Number needed to harm; MD: Mean difference

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GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

Explanations

- a. Studies taken from: Cochrane Review, Gulani 2012 (Bhandari 2002, Muller 2001)
- b. Indirectness: Population with likely endemic malnutrition and probable zinc deficiency. Not rated down.
- c. Imprecision: Optimal information size not reached, small event rates
- d. Studies taken from: Cochrane Review, Gulani 2012 (Bhandari 2002)
- e. Imprecision: Wide estimate of effect

References

1. Gulani A, Sachdev HS. Zinc supplements for preventing otitis media. The Cochrane database of systematic reviews. 2014(6):Cd006639. Epub 2014/06/30. doi: 10.1002/14651858.CD006639.pub4. PubMed PMID: 24974096.