

Summary of findings:




## 9. Vitamin D supplementation compared to placebo for prevention of acute otitis media

**Patient or population:** Children aged 1 to 5 years who are otitis prone (defined as at least 3 episodes of AOM in the preceding 6 months or at least 4 episodes in the preceding 12 months, with the most recent episode in the previous 2–8 weeks)

**Setting:** Primary health care.

**Intervention:** Vitamin D supplementation (1000 IU per day of Vitamin D<sub>3</sub>). Duration was for 4 months.)

**Comparison:** Placebo.

| Outcome<br>№ of participants<br>(studies)  | Relative effect<br>(95% CI)      | Anticipated absolute effects (95% CI) |                                   |  | Quality   | What happens  |
|--|----------------------------------|---------------------------------------|-----------------------------------|--|---|---|
|  |                                  | Without Vitamin D<br>supplementation  | With Vitamin D<br>supplementation | Difference   |   |   |
| >1 AOM episode<br>(includes AOMwiP and<br>AOMwoP)<br>assessed with: fever,<br>earache, irritability and<br>otoscopy +/-<br>tympanometry<br>follow up: range 1 to 6<br>months<br>№ of participants: 116<br>(1 RCT) <sup>1,a</sup> | <b>RR 0.68</b><br>(0.49 to 0.96) | 65.5%                                 | <b>44.6%</b><br>(32.1 to 62.9)    | <b>21.0% fewer</b><br>(33.4 fewer to 2.6<br>fewer) | <br>LOW <sup>b,c</sup>   | In otitis prone children treated with vitamin D<br>supplementation compared to placebo there<br>is possibly a reduction in AOM (includes<br>AOMwiP and AOMwoP) episodes at 1-6<br>months follow up.<br><br>NNT ~5 |
| >1 episode of AOMwoP<br>assessed with: fever,<br>earache, irritability and<br>otoscopy +/-<br>tympanometry<br>follow up: range 1 to 6<br>months<br>№ of participants: 116<br>(1 RCT) <sup>1,a</sup>                              | <b>RR 0.34</b><br>(0.19 to 0.64) | 50.0%                                 | <b>17.0%</b><br>(9.5 to 32.0)     | <b>33.0% fewer</b><br>(40.5 fewer to 18<br>fewer)  | <br>LOW <sup>b,c</sup> | In otitis prone children treated with vitamin D<br>supplementation compared to placebo there<br>is possibly a reduction in uncomplicated AOM<br>episodes at 1-6 months follow up.<br><br>NNT ~3                   |
| Adverse Events<br>(reported as<br>"significant", not<br>defined)<br>№ of participants: 116<br>(1 RCT) <sup>1,a</sup>   | not estimable                    | 0.0%                                  | <b>0.0%</b><br>(0.0 to 0.0)       | 0.0% fewer<br>(0 fewer to 0<br>fewer)              | <br>LOW <sup>b,c</sup> | In otitis prone children treated with vitamin D<br>supplementation compared to placebo there<br>is possibly no increase in on adverse events.<br><br>NNH Not evaluable  |

\*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

### 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. Study: Marchisio 2013
- b. Indirectness: Children studied during European winter (may not be applicable to warmer environments). Only children with rAOM studied.
- c. Imprecision: Single, small study

## References

1. Marchisio P, Consonni D, Baggi E, Zampiero A, Bianchini S, Terranova L, et al. Vitamin D supplementation reduces the risk of acute otitis media in otitis-prone children. *The Pediatric infectious disease journal*. 2013;32(10):1055-60. Epub 2013/05/23. doi: 10.1097/INF.0b013e31829be0b0. PubMed PMID: 23694840.