Effect of Vitamin D Supplementation in the Prevention of Recurrent Pneumonia in Under-Five Children – Correspondence 1

To the Editor: We read with interest the article on “Effect of vitamin D supplementation in the prevention of recurrent pneumonia in under-five children” published in IJP [1]. We felt that there are serious methodology issues in this article which warrant clarification from the authors.

The authors mentioned that it was a randomized controlled trial (RCT), however it doesn’t fulfil the basic criteria’s of an RCT. We applied the critical appraisal skills program checklist [2] for RCT’s and noticed following lacunae:

- a) The study doesn’t have a clear focused (PICO) question.
- b) There is no mention of calculation of sample size.
- c) There is no mention of randomization, allocation concealment, and blinding of intervention/assessment of outcome.
- d) There is no CONSORT flow diagram. So it leaves the reader to ponder about the adulteration and attrition.
- e) There is no mention of the method of analysis (Intention to treat/per protocol).
- f) In results, authors did not report the treatment effects along with estimates.
- g) There is no mention of the registration of the trial. The Declaration of Helsinki states that “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject” [3].

All these points clearly state that this study is more of a non-randomized trial rather than a planned RCT. Therefore appropriate changes must be made in methodology.

A significant proportion of the subjects in the control group were deficient in vitamin D at the enrolment itself. The authors didn’t supplement them despite knowing their deficient status and failed to check their vitamin D levels at the completion also. This raises serious concerns about the ethical issues in this trial [4].

We felt that the results are not presented in an appropriate way. The authors should have given results in the form of risk ratio with confidence limits for number of episodes of lower respiratory tract infection (LRTI) and in form of mean difference with 95%CI for LRTI duration. It would have helped the reader to make meaningful conclusions.

Despite the fact that there was no difference in the primary outcome in two groups, the authors mentioned (at many places) that administration of vitamin D in under-five children with pneumonia displayed beneficial effect. If the *p* value is not significant, then the straight forward implication is the null hypothesis is true and there is no benefit of the intervention. So the authors should refrain from concluding “Overall, the present study highlights that oral vitamin D has some beneficial effect” and should clearly state that this study failed to show any benefit of vitamin D mega dose for recurrent pneumonia in children.

The index study lacks the strengths of an RCT; therefore the results should be interpreted with a caution.

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