Reviewer's report

Title: Treatment of head lice with dimeticone 4% lotion: why was it more effective in a randomised controlled trial in rural Turkey than in England?

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Reviewer: Jorg Heukelbach

Reviewer's report:

In a comparative trial in Turkey, a 4% dimeticone product was compared to an alternative silicone treatment not further specified, for the treatment of head lice infestations. In general, the study methodology is sound and the manuscript is excellently written. There are some issues that need to be addressed in a revision of the manuscript.

Major Compulsory Revisions

1. Two products are compared, but none of them can be considered gold standard in Turkey and never have been tested in this country. The focus of this comparative trial should thus be on the comparative efficacy of both compounds (a new compound is slightly, but not significantly less effective than 4% dimeticone).

2. The authors compare the results with data from a previous study performed in Britain. However, results cannot be compared directly with this UK trial due to different clinical investigators, different recruitment methods of subjects, different parasite load of subjects before treatment, different socio-cultural settings, and slight differences in methodology such as diagnostic combing five times vs. four times, treatment at school vs. treatment at home etc. Thus, comparison of trials should be done in the discussion (and not the results) section.

3. Intervention: What is the alternative silicone product? Details must be given on the composition of the second compound, for interpretation of results. For the reader, it does not make a lot of sense comparing two products if the composition of one product is not known.

4. Discussion: „...the only salient difference between the groups (UK and Turkey) was the coverage of treatment within in the community.“ One of the main predictors for treatment success, the parasite load before treatment, was significantly different: Whereas 33% had a light infestation in UK, 83% and 75% presented with light infestation in Turkey! This should be discussed.

5. Authors' contributions:

According to the contributions statement, the study was performed by only four of the 13 authors of the manuscript. Contributions of the remaining nine authors need to be presented here.
Minor Compulsory Revisions

6. Background: It is in fact standard practice for RCTs of new treatments to be conducted in a completely different socio-cultural and geographical setting. Due to the differing resistance situation, this may be of particular importance in the case of pediculosis. However, I would have expected a comparative trial of the new treatment(s) as compared to the current gold standard therapy in Turkey. One product has been recently approved in Turkey, the other product tested is not yet on the market. Thus, there should be two objectives of the study: 1. Compare 4% dimeticone to an alternative formulation; 2. Assess the efficacy of 4% dimeticone in a different setting. The other issues should be discussed in the discussion section.

7. Community treatment: I am not convinced that offering treatment against head lice to the community was the main driving force for the excellent efficacies observed in the present trial. As prevalence in the community was low, transmission pressure in general is expected to be low. Transmission within the family is probably much more important than in the community outside the family. This should be clarified throughout the manuscript.

8. P.11, first para: Definition of intensity of infestation is presented in the results section. This should be moved to the methods.

9. Outcome: As dry combing is – besides a diagnostic tool – also a therapeutic method, care should be given in the number assessments. In total, dry combing was performed five times during a period of 14 days (1, 2, 6, 9, 14 days after first application). The study from England states that combing was performed merely on days 2, 6, 9 and 14 after first application. Thus, it is not clear if in fact similar study designs were used – this should be clarified.

10. British study: 2-3 strokes on each section were done to provide a „diagnostic“ snapshot – this is not clear in the Turkish study.

11. Results: As said, independent from community treatment, it is risky to compare trials from different socio-cultural settings, which in addition used different methods for recruitment of participants. Whereas the trial in Turkey is community-based, in Britain participants were recruited via newspaper and radio announcements. A bias towards more severe infestation is to be expected in the British study (Table 1 confirms this assumption). In addition, in the Turkish study recruitment was based on schoolchildren – even if their adult family members were also able to join in the study as participants.

12. Results - outcomes:
The phrase „None of the participants reported adverse events of any type.“ should be omitted, as adverse events are presented later in a separate subheading.

13. The entire paragraph „Comparison of these data with those obtained
previously......“ should be presented in the discussion section.

14. „Ovicidal success rate“ – this term is misleading and should be omitted. Data presented are not adequate to conclude on that. It is not known, how many participants with nymphs would have been observed in a negative control group where only combing was performed. Respective data should be presented in a more descriptive way, such as „in 28/36 (77.8%) no nymphs hatched after the first treatment....“

15. Are there any clinical secondary outcome measures?

16. The discussion is very much focused on the „prove“ that the relatively low efficacy in UK is caused by reinfestation. Reinfestation may be a reason for the improved efficacy in the Turkish trial as compared to the UK trial, but there are surely other factors that need to be discussed (see above), such as the lower parasite load in Turkey. In fact, this is not a surprise as in Turkey participants were recruited actively in the school/community whereas in Britain recruitment was passive, probably with a bias towards more complicated/heavy infestations. Without any doubt, family/community treatment increases the effectiveness of head louse control measures – but as said the success depends on a series of factors, such as prevalence, cultural habits etc.

17. Discussion: „We have also confirmed a suspicion that many of the apparent cases of treatment failure observed in UK studies were probably actually cases of reinfestation...“ – the current study indicates this to a certain extent, but as said above there are many other factors influencing the outcomes, and the present data situation is not sufficient to confirm this assumption definitely.

18. Conclusions: This section is summarizing the study- only conclusions of the trial should be presented (4% dimeticone vs. alternative silicone)

19. Table 1: Delete entire column „2005 study UK“. Include p values for baseline comparison of both intervention groups. Adapt title.

20. Table 2: Give exact p values instead of „not significant“ and „<0.05“. Include „...after 14 days in title“. Discretionary Revisions

21. Change title according to journal style (see instructions for authors) and CONSORT guidelines. Exclude also comparison with English trials from title.

22. Abstract: Background - delete „One explanation is that......treatment failure“ and „...for comparison with UK results. “

23. Methods - Participants: „A standard consent and assent procedure was followed to enable children and family members who had lice to receive treatment if they wished to participate in the study.“ The sentence should be rephrased as it seems that family members with lice who did not wish to participate were excluded from treatment.
Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.