Reviewer’s report

Title: The effectiveness of the biannual application of silver nitrate solution followed by sodium fluoride varnish in arresting early childhood caries in preschool children: A 30-month, randomised, double-blind, non-inferiority trial.

Version: 1
Date: 25 August 2015
Reviewer: Svetlana Tikhonova

Reviewer’s report:

Review (Svetlana Tikhonova), August 25th, 2015

Title: The effectiveness of the biannual application of silver nitrate solution followed by sodium fluoride varnish in arresting early childhood caries in preschool children: A 30-month, randomised, double-blind, non-inferiority trial.

Chun-Hung Chu *, Sherry Shiqian Gao, Samantha KY Li, May CM Wong, Edward CM Lo

The manuscript needs minor essential revisions.
Overall, the manuscript is focusing on the interesting and important topic and well written. The study design is appropriate to test the study hypothesis. However, some points should be considered before accepting the manuscript for publication.

Title:
1. In the study title you use the word ‘effectiveness’ while in the objective of the study the word ‘efficacy’ is used. These are two different things… please adjust in the manuscript.

2. I suggest to add in the title the words ‘primary teeth’

Abstract:
3. Please indicate the age of the study participants in the abstract.

Background:
Early childhood caries
4. I suggest to include the definition of the ECC in the study background since the ECC definitions are vary in the literature.

5. Also in this section it would be good to mention that the main treatment strategy for caries disease should be the non-operative strategy since the operative approach doesn’t treat the disease but lead to the re-restorative cycle.

Participants:
6. It seems for me that the points a)….‘aged 3-4 years who have a tooth decay’…
and d)’have at least 1 tooth with untreated caries…” are providing partly the same information, you just giving more details about caries in the point d).

7. ‘have at least 1 tooth with untreated caries that extends into the dentine’
Is it important which tooth surface will be involved?

8. ‘untreated caries that extends into the dentine’ is quite vague expression.
I suggest to be more specific regarding this. When you are talking about caries that extends into dentin are you based on clinical signs of dentin involvement?
Do you mean any caries lesions with dentin involvement seeing clinically? It can be non-cavitated lesions with shadows and other...

9. Are you including only the children who will have at the baseline active caries lesions with clinical dentin involvement? If yes, it should be clear in the inclusion criteria.

10. Regarding the exclusion criteria: will you include children with severe forms of hypoplasia of fluorosis, children with orthodontic devices?

Recruitment

11. Please, describe more precisely what is the initial oral examination and how it will be performed.

Clinical examination

12. Will the teeth being cleaned before the examination?
13. Will you apply the specific caries diagnostic criteria (e.g. WHO, 1997)?

14. ‘The caries will be diagnosed at the cavitation level.’ Please specify: are you talking about any cavitated lesion – microcavitated and with a frank cavitation?

15. If the dentin of the caries lesion will have a ‘leathery’ texture, how would you define this lesion (active or arrested)?

Questionnaire

16. I suggest to include the questionnaire into the manuscript

Randomization and treatment allocation

17. Why before the allocation you first categorizing children as having high or low caries rate?

Interventions

18. Is there a possibility that the placebo petroleum jelly varnish may influence on the effect of 38% SDF solution?

Statistical analysis

19. The effect of the treatment may also depend on the tooth surface where the
treatment will be applied.

20. What are the potential limitations of the study?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:

I declare that I have no competing interests.