Reviewer’s report

Title: A new non-invasive approach based on polyhexamethylene biguanide increases the regression rate of HPV infection

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Reviewer: Nils-Olaf Hübner

Reviewer’s report:

Reviewer’s comments

“A new non-invasive approach based on polyhexamethylene biguanide increases the regression rate of HPV infection”

The authors report experiences from a clinical trial with a commercial PHMB product against HPV-infection. They found a statistically significant reduction in the treatment group compared to control.

Major comments

Protocol
- The point “Randomization” should be explained further
- What was the idea behind the study? Was it a hypothesis-generating study, a confirmatory study…? 
- No data on an a-priori power-analysis is given Why were 100 women selected, not 110, 180, or 92?
- How big was the expected effect size?
- No data on social or medical data of the participants or of differences between groups are reported. As regression of HPV is a complex process this could be important, could it be not?
- What is the actual formulation of Monogin? What are the active ingredients?
- How and by whom was the solution applied?

Statistics
I simply do not understand the statistics used.
- What was the t-test used for?
- I can find no results from the t-test….
- Where the assumptions for a parametrical test met?
- What was the ANOVA used for?
- I can find no results from the ANOVA….
- Where the assumptions for an ANOVA met?
As I understand the study, the results are nominal (e.g. HPV DNA y/n) therefore statistics for nominal data not parametric tests for metric data should be used! E.g. cross tabs (as already included!) with Fisher’s exact test/RR for example.

Results
- Please edit the results section in accordance with the statistics!
- A quick calculation for RRs based on tables 1 and 2 seems to indicate a very small true effect in favor of the treatment group (1.28 [CI95: 1.05-1.58]) in the long term but not in the short term (1.18[CI95:0.86-1.62]).
- The last sentence is contradictory to the rest of the manuscript

Discussion
- The formulation of Monogin should be reported, as the effects of more than one active ingredient are discussed
- As the study lasted only 6 month the conclusions on safety are too strong
- To conduct that PHMB is indicated as treatment based on one, relatively small study with a product containing more than one active ingredient is not adequate

The tables are good and can be extended with statistics. The figures should be omitted.

Minor comments
There are some small grammatical flaws throughout the text.

Methods
- Inclusion and exclusion criteria should be separated in two sentences

This an interesting study and promising antiseptic approach. The manuscript unfortunately has many flaws and will need extensive and meticulous revision before being publishable.

Level of interest: An article of importance in its field

Quality of written English: Needs some language corrections before being published

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that my former working group has received a research grant from LoLiPharma, manufacturer of Monogin, in the past.