Reviewer's report

Title: Safety and efficacy of wiping lid margins with lid hygiene shampoo using the “Eye Brush”, a novel lid hygiene item, in healthy subjects: A pilot study

Version: 0 Date: 02 Dec 2018

Reviewer: Research Square

Reviewer's report:

"STATISTICAL REVIEWER ASSESSMENT:

Is the study design appropriate for the research question (considering whether the analyzed population accurately reflects the design and whether you see any problems with control/comparison groups, e.g., likely confounders)?

No - there are major issues

Are methodologies adequate and well implemented (considering whether assumptions are addressed and whether analyses are robust)?

No - there are major issues

Are the analyses adequately communicated (considering whether reporting details are adequate and whether figures and tables are well labeled and described)?

No - there are major issues

Does the interpretation accurately reflect the analyses without overstatement (considering whether limitations/bias are acknowledged and whether accurate descriptors, e.g., 'significant', are used)?

No - there are major issues

Could an appropriately REVISED version of this work represent a statistically sound contribution?

Maybe - with major revisions
STATISTICAL REVIEWER COMMENTS:

The authors evaluate a novel eyebrush to improve lid hygiene and show that a combination of the eye brush with eye shampoo yielded the best results. I have certain reservations about the study.

REQUESTED REVISIONS:

Abstract: The methods section is a bit unclear. Were all 12 eyes (of 6 patients) given all 4 of the interventions, or were the interventions equally divided amongst the eyes? Also, the term "Eye brush" is new and gives the impression that it is a device to apply something such as eye shampoo or perhaps, another solution. Hence, it is confusing that there is one group of only eye brush. Was this not combined with anything to apply?

The results section does not make much sense in this context. Since these were healthy subjects, how did eyestrain and discharge decrease? Are these not asymptomatic to begin with? The authors should also clarify in the abstract itself how a washout rate of 0.3% Tarivid ophthalmic ointment (a surrogate for wiping efficacy) was actually measured.

Main manuscript body:

The sample size is exceedingly small to draw meaningful conclusions.

It appears that the same eyes were subjected to all the groups with change over every week into the next protocol. What is the rationale of using the same eyes for all interventions? It may have been better to recruit more subjects and give one group to one set of subjects.

When was the evaluation done for the tap water, eye brush and eye shampoo groups?

What is the chemical content of Tarivid ointment? Please clearly specify whether it is Ofloxacin ointment or not.

All the scoring systems appear subjective and are not standardized, which is open to individual interpretation. This requires more than one investigator to see the eye and grade the various tests.

Was there any masking in the study protocol? If we assume that the Tarivid ointment was applied on the first day of every protocol and not daily, then at the 7th day, a masked grader who
is unaware of the exact treatment used, should have graded the outcomes and scored the tests. The absence of masking is a major limitation of the study, though the authors acknowledge this.

The details of Bonferroni correction and p value cut offs should be part of the statistical analysis section.

Since there are 4 tests for each group and each test has a separate score, did the authors combine the scores from all tests to arrive at one composite score (wiping efficacy) and calculate statistical differences? Please specify this in the methods section, i.e., how were scores from different investigative modalities combined? The results can be held credible only when this point is clarified by the authors. The authors should also mention the one month outcomes of the combined group.

ADDITIONAL REQUESTS/SUGGESTIONS:

The authors should include the small sample size as a limitation for the study."

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.
No

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.
No

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.
No

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.
I am able to assess the statistics

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