Reviewer’s report

Title: Sunflower oil and Mustard oil: Skin barrier function in newborns via a community-based, cluster randomized trial

Version: 0 Date: 04 Sep 2019

Reviewer: Suzanne Pasmans

Reviewer's report:

The authors aimed to quantify differences in skin barrier integrity and maturation between newborns randomly assigned to routine massage with mustard oil or sunflower seed oil over the first postnatal month, using skin condition (erythema, rash, dryness), skin surface pH, stratum corneum cohesion/protein concentration, and transepidermal water loss parameters.

We think this paper is novel and relevant for low resource settings. Furthermore, it is important to get insight in low-cost preventive strategies to improve morbidity and mortality due to skin infections. The impact of these data for Western countries could be improved by addition of a control group without oil exposure or a group with emollient therapy.

Methods section

- Please consider to delete information about the skin condition (erythema, rash, dryness) as this raises questions about the infection rate/mortality due to skin infections in both intervention groups. Otherwise, provide information about the infection rate in this manuscript.

- Page 6, line 18-22: Please provide the name of the validated scoring scales for erythema, rash and dryness or add the scale to the supporting information. Could you explain the differences between scoring of rash and erythema?

- Page 6, statistical analysis: Did you perform a sample size calculation, if so please elaborate on this.
- Page 7, ethical approval: Please explain why no permission was needed from father and why only verbal (not written) informed consent was provided.

Results section

- Page 8, line 38-39: The proportions of preterm infants in the MO (45.4%) and SSO (39.9%) groups do not correspond with the percentages of preterm (&lt;37 weeks) patients in Table 1: 11.2+29.7=40.9% in the MO group and 11.4+28.3=39.7% in the SSO group. Please explain the differences.
- Page 8, line 43-44: Please explain compliance with oil application and massage. Based on which data did you calculate the 100% compliance? What were the massage frequencies after the first week, were they similar between the intervention groups (in the manuscript you only address the frequencies during the first week)?

Discussion

- What was the rationale behind the 28 days-intervention period in relation to skin barrier integrity and maturation? Do you expect changes between the groups after 1 month application of oil?

- Page 11, line 48-51, "Regardless of... in severity": Is it possible that the worsening of skin condition is due to the oil and/or massage independent of the type of oil? You did not include a control group, so you cannot exclude that the worsening is due to the oil exposure.

- Page 13, line 16-17: Please consider to delete the sentence "Such information... is universal". In our opinion this is not a practical study (like the parent study) as you only quantify skin barrier integrity and maturation using skin surface pH, SC cohesion/protein concentration, and TEWL in this nested study. Including a control group without oil application would be of interest as this gives insight in the mode of action of the oils.

Tables/figures

- Table 1: Please consider to delete the characteristic "has electricity" or otherwise explain the relevance.

- Table 2: Could you merge the scores per skin location into a general score of erythema, rash and dryness? Scores per skin location could be added to the supporting information.

- Figure 1: Do the "clusters" in figure 1 correspond to the "sectors" at page 5, line 14? Please use the same terms.

- Figure 1: The use of "n=" for both cluster numbers and patient numbers is confusing. Please adjust for this and change "eligible for mechanisms sub study" into "clusters eligible for..." and "mustard oil"/"sunflower oil" into "clusters assigned to mustard oil/sunflower oil".

- Figure 1: In the "selected" box "n=" is missing in both intervention groups.

- Figure 2: Please match the y-axis scales of mustard oil and sunflower oil (0 is not on the same height).

General

- Please use line numbers in following submission.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

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.

Yes

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 recommend additional statistical review

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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