Reviewer’s report

Title: Safety and immunogenicity of a varicella vaccine without human serum albumin (HSA) versus a HSA-containing formulation administered in the second year of life: a phase III, double-blind, randomized study

Version: 0 Date: 17 Dec 2018

Reviewer: Tetsushi Yoshikawa

Reviewer’s report:

Faust et al. demonstrate results of Phase III, double-blind, multicenter study for evaluation of safety and immunogenicity of the live-attenuated varicella vaccine produced without human serum albumin (HSA). Their data demonstrated that the varicella vaccine formulated without HSA was safe and highly immunogenic as the previous vaccine with HSA. This study is well organized and highly reliable.

Specific comments

1. Page 5, last line: I think that Figure 1 is not necessary.

2. Page 7, lines 17: Did authors carry out molecular analysis to determine whether varicella like skin rash caused by varicella vaccine or not?

3. Page 7, line 23: The authors demonstrated that blood samples were collected before and 42 days after vaccination. Were all of post vaccination samples collected at 42 days after the two doses of vaccinations?

4. Page 9: Table 1 should be moved to after the main text.

5. Additional tables should be used as the regular Tables. And, tables A1_2 and A1_3 should demonstrate as similar to the Table A1_1. Difference should be described in the Table. Although all data were not statistically difference, it should be added in explanations.

6. It is difficult to understand Figure 2. Did authors use data collected from patients administered of forbidden vaccine, or the patients with concomitant infection? The author should clearly explain the issue in the text.

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.

Yes

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

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Please indicate the quality of language in the manuscript:

Acceptable

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