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Comments on: a phase 1/2a, dose-escalation, safety and preliminary efficacy study of oral therapeutic vaccine in subjects with cervical intraepithelial neoplasia 3

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With great interest, we read the recently published article by Park et al. [1] titled "A phase 1/2a, dose-escalation, safety and preliminary efficacy study of oral therapeutic vaccine in subjects with cervical intraepithelial neoplasia 3." The authors reported safety and efficacy study of oral therapeutic vaccine BLS-M07 to treat cervical intraepithelial neoplasia 3 (CIN3). Despite its strengths, 2 technical issues should be considered.

Firstly, the key point of this study is human papillomavirus 16 (HPV16) E7-specific immunoglobulin G (IgG) titers in plasma [2]. According to the manuscript, "Between April 2014 and March 2016, 19 patients with single infection of HPV16 were enrolled in the study", the study conducted between 2014 and 2016. Furthermore, blood samples were collected at week 1, 9, and 16 and HPV16 E7-specific IgG were detected in the plasma. The testing time of plasma samples were not included in the manuscript. Were the plasma samples tested throughout the study or were they tested at the same time? The storage conditions of the plasma samples were not introduced in the "MATERIALS AND METHODS". Although the plasma samples were stored at −20°C, the HPV16 E7-specific IgG titers may degrade during the period of 2 years. The stability of the level may influence the results of the study. A study explored the impact of storage conditions and the use of labile serum factor (LSF) against selective arboviruses in infected humans. The neutralization-enhancing effect of LSF was absent in serum stored at 24°C for 15 days [3].

Secondly, the baseline titers of HPV16 E7-specific IgG titers of 19 patients should be performed before the study, and the titers are the foundation of seroconversion. Notably, the relationship between HPV16 E7-specific IgG titers and storage conditions should be further investigated based on the long-term stored samples. If the seropositive sample was still stored, a testing should be performed in the future.

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Author Contributions

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