Title of Research:

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The validation study of EpiSensA (Epidermal Sensitization Assay); the *in vitro* skin sensitization assay based on reconstructed human epidermis

Principal Investigator:

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Summary of Research:

Lipophilic chemicals are difficult to correctly evaluate by existing in vitro tests because these tests employ aqueous-phase systems. To overcome the limitation, we focused on a reconstructed human epidermis (RhE) and developed the Epidermal Sensitization Assay (EpiSensA) based on the expression of four marker genes related to induction of skin sensitization. Based on the comparison with the results of animal test, we confirmed that EpiSensA has better predictive performance for a variety of chemicals including lipophilic chemicals than existing in vitro tests. Therefore, the validation study of EpiSensA was started from July 2018 at JaCVAM (Japanese Center for the Validation of Alternative Methods) to adopt it for OECD test guideline. We have reported that the validation management team (VMT) concluded the technical transfer from the lead laboratory to three participating laboratories (Food and Drug Safety Center, KOSÉ Corporation and LION Corporation) was successfully completed.

For evaluation of within laboratory reproducibility (WLR), three laboratories test 15 coded chemicals in three independent experiments each. This Phase I was conducted in three parts (Phase I-A, I-B, and I-C), each including 5 chemicals. The Phase I-A and I-B were finished, and subsequent Phase I-C was performed. As a result, the WLR was not confirmed at one out of the five test chemicals in two laboratories, so the data analysis of the chemical was performed. In consequence, it was confirmed that the cross-contamination of volatile strong sensitizer was the cause of unreproducible result. Therefore, protocol modification was proposed to avoid the potential cross-contamination effect of volatile strong sensitizers, and approved by the VMT. Finally, the WLR using 15 coded test chemicals satisfied the target criteria or 85% in all laboratories. The validation management team concluded that the entire Phase I study was completed successfully.

Timeline:

March 1, 2020 - February 28, 2021

Topics:

Oral presentation at JCIA LRI Annual Workshop 2020 “The validation study of EpiSensA (Epidermal Sensitization Assay); the in vitro skin sensitization assay based on reconstructed human epidermis” (On-line, August 21st, 2020)

Publications:

The 33rd Annual Meeting of the Japanese Society for Alternatives to Animal Experiments, On-line, Japan, Nov. 2020.