Safety and Efficacy of LC16m8, a live, attenuated, cell-cultured smallpox vaccine

How can we evaluate the safety and efficacy of LC16m8, after the elimination of the disease?

Background

-WHO declared the elimination of smallpox in 1980.

-Prior to it, the Japanese government seized the smallpox vaccination in 1976.

-After the 2011 attack in the USA, we restarted the production of LC16m8 and stocked it as anti-terrorism measures.

-LC16m8 was licensed in 1975, , however, it has not been use in the smallpox elimination campaign until 70's.

-Thus, evaluation of safety and efficacy of LC16m8 is required by comparing its inducing immune responses with those by the 1st generation vaccines.

Vaccination



Smallpox vaccination



Bifurcation needle (JMS)

Safety and Efficacy

Adverse effect Take Neutralizing antibody titers

Proteome-wide measurements of antigen-specific antibodies after vaccination (Illustration)



Data analysis

LC16m8 vs 1st-generation vaccine Primary vaccinees vs revaccinees Effect of dose of administration Effect of pre-existing immunity derived from vaccination(s) until 70s PRNT-contributing antigens PRNT against various strains Antibodies important for long-immunity Antibody production in animal models

[Publication]

Recent advances in the study of live attenuated cell-cultured smallpox vaccine LC16m8. Eto A, Saito T, Yokote H, Kurane I, Kanatani Y. Vaccine. 2015 Nov 9;33(45):6106-11. Review. PMID: 26319072

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