DSEN ABSTRACT

Safety of live, replicating smallpox vaccine in contraindicated populations: A systematic review

Summary

- We conducted a systematic review to summarize the comparative harms of prophylaxis using live, replicating smallpox vaccines in contraindicated populations.
- Data were insufficient to inform the planned network meta-analysis.

Key messages

- Although this systematic review does not change the overall understanding of the relative risk of SAEs associated with live, replicating smallpox vaccines in contraindicated populations, it does provide an updated compilation of the evidence base and identify important knowledge gaps.

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What is the issue?

- Despite the eradication of smallpox decades ago, public health officials remain vigilant in their emergency preparedness efforts.
- Relatively high proportions of the population are advised against taking live, replicating smallpox vaccination in non-emergency situations due to rare yet severe adverse events (SAEs).
- Although attenuated vaccines have fewer known safety concerns, availability and resource limitations necessitate population use prioritization.

What was the aim of the study?

- The objective of this project was to summarize the comparative harms of prophylaxis using live, replicating smallpox vaccines in contraindicated populations including individuals with systemic hypersensitivity, exfoliative dermatologic condition, cancer, heart disease, HIV/AIDS and cardiac risk factors or who were immunocompromised/suppressed or pregnant/nursing.

How was the study conducted?

- This study was conducted using a systematic review methodology. We searched seven bibliographic databases (April 2020) for randomized, non-randomized or observational studies comparing contraindicated population exposure to live, replicating smallpox vaccine (1st or 2nd generation) to no vaccine, alternative vaccination strategy or attenuated (3rd generation) smallpox vaccine.
- Outcomes of interest were progressive vaccinia, eczema vaccinatum, clinically-severe inadvertent inoculation, postvaccinial central nervous system disease, vaccine-attributable death and cardiovascular outcomes.

What did the study find?

- A total of 353 records were included, of which 105 reported data. No comparative evidence was available, so effect estimates were calculated for the prevalence of rare or serious adverse outcomes in the contraindicated groups of interest.
- Very little data were reported for most contraindicated populations. Planned quantitative analyses were not feasible. Prevalence of outcomes with available data varied by population group and SAE frequencies were relatively low.

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CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

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