PROTOCOL BRIEF

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Efficacy, effectiveness, and safety of herpes zoster (HZ) vaccines in individuals 50 years of age and older: a systematic review protocol

Rationale

Herpes zoster (HZ) occurs through a reactivation of the latent varicella zoster virus. In Canada, a live-attenuated vaccine has been approved for HZ for adults aged 50 years or older. However, vaccine efficacy decreases for those aged 70 years or greater and its use is contraindicated for immunosuppressed individuals. We aim to assess the efficacy, effectiveness, and safety of all available HZ vaccines for adults aged 50 years and older through a systematic review.

Implications

One fourth of people are at risk of developing HZ during their lifetime, and two thirds of all people who contract HZ are adults aged 50 years or greater. The morbidity of HZ is greater as we age. This review will synthesize existing evidence on efficacy, effectiveness and safety of all HZ vaccines. Findings from this review will be used by National Advisory Committee on Immunization to formulate recommendations on the zoster vaccines.

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Background

- The morbidity of HZ is greater (e.g. post-herpetic neuralgia) as we age, and vaccine efficacy has been shown to decrease with age and is contraindicated for immunosuppressed individuals. In Canada, a live-attenuated vaccine is approved for HZ for adults aged 50 years or older.

Objective

- To assess the efficacy, effectiveness, and safety of the live herpes zoster (HZ) vaccine (currently authorized in Canada) compared to the subunit vaccine (recently submitted for approval) or placebo/no intervention for individuals aged 50 years and older.

Methodology

- A systematic review will be conducted, following the methods proposed in the Cochrane Handbook for Systematic Reviews
- Our eligibility criteria are outlined using the PICOS framework, as follows:

  Population: *All adults aged 50 years and older.*

  Intervention: *Live attenuated HZ vaccine approved in Canada.*

  Comparator: *HZ subunit vaccine (1 or 2 doses), sham (or placebo vaccine), no intervention, or another HZ vaccine (including those not currently available clinically), dosage comparison of the same vaccine.*

  Outcomes: *Vaccine efficacy (herpes zoster disease incidence [primary outcome]), effectiveness, quality-of-life and harms (e.g., injection-site and systemic reactions)*

  Study designs: Randomized controlled trials (RCTs) and non-randomized studies (e.g., observational studies for harms outcomes)

- The literature search will be executed in: MEDLINE, EMBASE, and the Cochrane Library. Grey literature will be searched (e.g. clinicaltrials.gov). Title and abstract screening, full-text screening, and data abstraction will be conducted in duplicate. All discrepancies will be resolved by discussion or by a third reviewer.
- Included studies will be charted according to participants, interventions, comparators, and outcomes. The risk of bias in the included RCTs will be appraised using the Cochrane risk of bias tool and the Newcastle Ottawa Scale for observational studies by two reviewers, independently. Data will be synthesized and statistical analysis conducted for treatment comparisons. Subgroup analysis is planned for age groups, healthy vs. immunocompromised vs. non-immunocompromised with comorbid conditions, sex, and previous HZ infection vs. HZ-naïve.

Knowledge Translation Strategy

- We will publish our final results in an open-access, peer-reviewed journal, prepare a 1-page policy brief and present our findings to Public Health Agency of Canada, National Advisory Committee on Immunization Secretariat and working group, and other relevant Drug Safety and Effectiveness Network decision-makers.

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