INPLASY

Evaluating the Efficacy and Safety of the Fourth COVID-19 Vaccine Dose: A Comprehensive Meta-Analysis Across Diverse Populations

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ADMINISTRATIVE INFORMATION

Support - Peking University Shenzhen Hospital.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 November 2023 and was last updated on 20 November 2023.

INTRODUCTION

Review question / Objective Does the administration of a fourth dose of COVID-19 vaccines significantly reduce the risk of SARS-CoV-2 infection, hospital admission, and death compared to only three doses, and what is its safety profile across diverse populations?

Condition being studied Condition/Disease: COVID-19 (Coronavirus Disease 2019).

METHODS

Participant or population Individuals who have received three or four doses of COVID-19 vaccinations.

Intervention Administration of the fourth dose of COVID-19 vaccines.

Comparator Individuals who have received only three doses of COVID-19 vaccines.

Study designs to be included Inclusion of longitudinal and randomized controlled trial (RCT) studies, as well as observational studies where applicable.

Eligibility criteria Published articles were eligible for this study if they meet the following inclusion criteria: (1) observational studies (prospective or retrospective cohort) or RCTs with a minimum of 10 general adult participants in any study group; (2) at least involved one type of the fourth dose COVID-19 vaccination after three dose vaccination; (3) a control group comprising participants who completed full COVID-19 vaccination and receive one booster dose; and (4) reported at least one of the outcomes of interest in both the four dose group and three dose group:

laboratory-confirmed infection, COVID-19-related hospitalization, COVID-19-related death. We did not include the following studies:(1) the studies did not have baseline data; (2) review studies; and (3) meta-analysis (4) case reports (4) non-English publications.

Information sources Relevant studies that were published in PubMed, Embase, Web of Science.

Main outcome(s) Comparison of the three main outcomes, i.e. laboratory-confirmed COVID-19 infection, COVID-19-related hospitalization and COVID-19-related death.

Additional outcome(s) Safety of vaccination.

Quality assessment / Risk of bias analysis Risk of Bias in Non-randomized Studies of Interventions (ROBINS-I).

Strategy of data synthesis Used Mantel-Haenszel method and the DerSimonian and Laird random-effects model to estimate the pooled risk ratio (RR).

Subgroup analysis subgroup like sex, age, region, vaccine type will be analyzed.

Sensitivity analysis leave-one-out sensitivity analysis using the random-effects DerSimonian-Laird model.

Language restriction English.

Country(ies) involved China.

Keywords COVID-19 Vaccination; Fourth Dose; mRNA Vaccines; Vaccine Safety Profile; Meta-Analysis.

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