INPLASY PROTOCOL

To cite: Zhao et al. Efficacy and Safety of COVID-19 Vaccines among People Living with HIV:A Meta-Analysis. Inplasy protocol 202330092. doi: 10.37766/inplasy2023.3.0092

Received: 24 March 2023

Published: 24 March 2023

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Support: **None.**

Review Stage at time of this submission: **Formal screening of search results against eligibility criteria.**

Conflicts of interest:
None declared.

Efficacy and Safety of COVID-19 Vaccines among People Living with HIV:A Meta-Analysis

Zhao, TY[1]; Chen, HF[2]; Yang, J[3].

Review question / Objective: **To evaluate the efficacy and safety of COVID-19 vaccines among People Living with HIV by meta-analysis.**
Eligibility criteria: **Inclusion criteria(1) studies reporting PLWH receiving any COVID-19 vaccines who had never been infected with SARS -CoV-2; (2) studies with extractable data on seroconversion rates, GMT, and incidence rates of adverse events; (3) observational studies (cross-sectional studies, case-control studies, and cohort studies), non-randomized clinical trials, and RCTs.Exclusion criteria(1) non-original articles such as reviews, comments, letters, etc.; (2) articles unable to find full text; (3) preprints;(4) studies with insufficient data to calculate the seroconversion rate and incidence rate of adverse events.(5) studies thet reported serological titres in a form from which neither mean nor median titres could be derived.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 24 March 2023 and was last updated on 24 March 2023 (registration number INPLASY202330092).

INTRODUCTION

Review question / Objective: **To evaluate the efficacy and safety of COVID-19 vaccines among People Living with HIV by meta-analysis.**

Condition being studied: **The primary outcome to evaluate the efficacy of COVID-19 vaccines was the seroconversion of neutralizing antibodies to SARS-CoV-2 after a first or second dose, defined as a change from seronegative at baseline to seropositive.**

METHODS

Search strategy: Pubmed
("Coronavirus Infections"[MeSH] OR "Coronavirus"[MeSH] OR "SARS-CoV-2"[MeSH] OR "COVID-19"[MeSH] OR "2019 nCoV"[All Fields] OR 2019nCoV[All Fields] OR coronavir*[All Fields] OR coronovir*[All Fields] OR COVID[All Fields] OR COVID19[All Fields] OR HCoV*[All Fields] OR "nCov 2019"[All Fields] OR "SARS CoV2"[All Fields] OR "SARS CoV 2"[All Fields] OR SARSCoV2[All Fields] OR "SARSCoV 2"[All Fields] OR "severe acute respiratory syndrome coronavirus 2"[All Fields])
AND
("HIV"[MeSH] OR "HIV infections"[MeSH] OR "anti-HIV agents"[MeSH] OR "HIV protease inhibitors"[MeSH] OR "reverse transcriptase inhibitors"[MeSH] OR HIV*[All Fields] OR human immun*[All Fields] OR "acquired immunodeficiency syndrome"[All Fields] OR "acquired immune deficiency syndrome"[All Fields] OR HIV infect*[All Fields] OR AIDS[All Fields])
AND
("Vaccines"[MeSH] OR "Vaccination"[MeSH] OR Vaccin*[All Fields])
Embase
('coronavirus Infection'/exp OR 'coronavirinae'/exp OR 'coronavirus disease 2019'/exp OR 'severe acute respiratory syndrome coronavirus 2'/exp OR 'coronavirinae' OR 'coronavirus Infection' OR 'coronavirus disease 2019' OR 'severe acute respiratory syndrome coronavirus 2' OR 'sars-cov*' OR 'coronavir*' OR 'covid*')
AND
('human immunodeficiency virus'/exp OR 'human immunodeficiency virus infection'/exp OR 'anti human immunodeficiency virus agent'/exp OR 'human immunodeficiency virus proteinase inhibitor'/exp OR 'acquired immune deficiency syndrome'/exp OR 'human immunodeficiency virus' OR 'human immunodeficiency virus infection' OR 'HIV*' OR 'human immun*' OR 'acquired immune deficiency syndrome' OR 'AIDS')
AND
('vaccination'/exp OR 'vaccine'/exp OR 'vaccin*')
NOT [medline]/lim
Cochrane Libarary
("Coronavirus Infections"[MeSH] OR "Coronavirus"[MeSH] OR "SARS-CoV-2"[MeSH] OR "COVID-19"[MeSH] OR coronavir* OR covid-19 OR sars-cov* OR severe acute respiratory syndrome coronavirus 2)
AND
("HIV"[MeSH] OR "HIV infections"[MeSH] OR "anti-HIV agents"[MeSH] OR HIV* OR human immun* OR acquired immune deficiency syndrome OR AIDS)
AND
(vaccin*).

Participant or population: PLWH receiving any COVID-19 vaccines who had never been infected with SARS -CoV-2.

Intervention: People Living with HIV after the vaccine.

Comparator: The seropositivity rate of healthy controls who after COVID-19 vaccines.

Study designs to be included: Any comparative human study, either observational or experimental.

Eligibility criteria: Inclusion criteria(1) studies reporting PLWH receiving any COVID-19 vaccines who had never been infected with SARS -CoV-2; (2) studies with extractable data on seroconversion rates, GMT, and incidence rates of adverse events; (3) observational studies (cross-sectional studies, case-control studies, and cohort studies), non-randomized clinical trials, and RCTs.Exclusion criteria(1) non-original articles such as reviews, comments, letters, etc.; (2) articles unable to find full text; (3) preprints;(4) studies with insufficient data to calculate the seroconversion rate and incidence rate of adverse events.(5) studies thet reported serological titres in a form from which neither mean nor median titres could be derived.

Information sources: Database: PubMed, Embase, and Cochrane Library.

Main outcome(s): Efficacy, including but not limited to anti-SARS-CoV-2 immunoglobulin levels, seroconversion, neutralizing activity levels. Adverse events incidence.

Additional outcome(s): None.

Quality assessment / Risk of bias analysis: The risk of bias in the included studies will be independently assessed by two reviewers.We evaluated the risk of bias using the Revised Cochrane risk-of-bias tool for randomized trials (RoB 2) for RCTs, Risk Of Bias In Non-randomized Studies of Interventions (ROBINS-I) tool for non-randomized clinical trials, Newcastle–Ottawa scale for cohort studies and case-control studies, and Agency for Healthcare Research and Quality (AHRQ) for cross-sectional studies.

Strategy of data synthesis: STATA version 17 for Windows and Review Manager version 5.2 software were utilized for the meta-analysis.We used a random-effects model to estimate the pooled risk ratios (RRs) and corresponding 95% confidence intervals (CIs) for the primary outcomes of inter- est. An RR < 1 indicates that PLWH had a lower risk of achieving seroconversion after COVID-19 vaccination than the control groups. The heterogeneity of studies was measured using I2 test. We considered heterogeneity to be significant when the I 2 statistic was 50% .Also, based on the heterogeneity of studies, either meta-regression analysis or subgroup analysis was performed for potential moderators. Besides, funnel plot asymmetry and the Eggers test were used to assess publication bias.

Subgroup analysis: Subgroup analysis will be done based on geographic location, study design, vaccine type, and CD4+ T-cell counts.

Sensitivity analysis: Through excluding studies with a high risk of bias, make the results stable.

Language restriction: No.

Country(ies) involved: China.

Other relevant information: None.

Keywords: COVID-19; vaccines; people living with HIV; efficacy; safety.

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