

INPLASY PROTOCOL

To cite: Malipati et al. Efficacy and safety of Tenofovir alafenamide in blocking mother-to-child transmission of hepatitis B virus: a meta-analysis. Inplasy protocol 2022110061. doi: 10.37766/inplasy2022.11.0061

Received: 13 November 2022

Published: 13 November 2022

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Support: None.

Review Stage at time of this submission: Preliminary searches.

Conflicts of interest:
None declared.

Efficacy and safety of Tenofovir alafenamide in blocking mother-to-child transmission of hepatitis B virus: a meta-analysis

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Review question / Objective: The study is to evaluate the efficacy of TAF in preventing perinatal HBV transmission, as well as monitoring safety for mothers and infants.

Condition being studied: The vertical transmission of HBV from mothers to their infants at birth or in early infancy has a significant role in the endemicity of HBV infection. Few safety and effectiveness results have been published regarding the administration of tenofovir alafenamide fumarate (TAF) during pregnancy for the prevention of mother-to-child transmission (MTCT) of hepatitis B virus (HBV).

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 November 2022 and was last updated on 13 November 2022 (registration number INPLASY2022110061).

INTRODUCTION

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prevention of mother-to-child transmission (MTCT) of hepatitis B virus (HBV).

METHODS

Participant or population: Pregnant women who had chronic HBV infection, were HBeAg-positive.

Intervention: TAF treatment.

Comparator: None(single-arm clinical trail).

Study designs to be included: randomized controlled trial (RCT), or case-control study, or cohort study.

Eligibility criteria: Pregnant women who had chronic HBV infection, were HBeAg-positive and a new-born infant.

Information sources: The Cochrane Library, Embase, PubMed, China National Knowledge Infrastructure (CNKI), Wanfang and China Biomedical Literature Database (CBM).

Main outcome(s): mother to child transmission rate, maternal HBV-DNA levels, maternal and infant safety outcomes.

Quality assessment / Risk of bias analysis: The quality of non-randomized studies was assessed using a modified Newcastle-Ottawa scale (NOS).

Strategy of data synthesis: The present meta-analysis was conducted using the RevMan 5.3 software offered by Cochrane Collaboration. The Relative risk ratio (RR) was used as the effect size for dichotomous variables, and their pooled effect size and its 95% Confidence Interval (CI) were also calculated. Heterogeneity noted across all study results was evaluated using the χ^2 test, and the size of heterogeneity was quantitatively determined in combination with I^2 . If there was no statistical heterogeneity across the study results ($P > 0.10$, $I^2 \leq 50\%$), a fixed effect model was used for the meta-analysis. However, when

there was statistical heterogeneity across the study results ($I^2 > 50\%$), a random-effect model was used for the meta-analysis.

Subgroup analysis: None reported.

Sensitivity analysis: Sensitivity analysis was performed on the included indicators. The results of the new Meta-analysis, in which a certain study was excluded one by one, were unchanged, which proved that the results of Meta-analysis were relatively stable.

Country(ies) involved: China.

Keywords: Hepatitis B; Tenofovir alafenamide; Mother-to-child transmission; meta-analysis

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