

# INPLASY PROTOCOL

To cite: Wang et al. Isoniazid Preventive Therapy in HIV-Infected Pregnant and Postpartum Women in high prevalence of tuberculosis countries: a protocol for systematic review. Inplasy protocol 202070011. doi: 10.37766/inplasy2020.7.0011

Received: 03 July 2020

Published: 03 July 2020

**Corresponding author:**  
Xiaozhuan Wang

jl9300874@gmail.com

**Author Affiliation:**  
Gansu Provincial Maternity  
and Child-care Hospital

**Support:** Gansu national  
Science.

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

**Conflicts of interest:**  
The authors have no conflicts of interest to declare.

## INTRODUCTION

**Review question / Objective:** Is Isoniazid Preventive Therapy effective and safe for preventing Tuberculosis in HIV-Infected

## Isoniazid Preventive Therapy in HIV-Infected Pregnant and Postpartum Women in high prevalence of tuberculosis countries: a protocol for systematic review

Wang, XZ<sup>1</sup>; Zhang, Y<sup>2</sup>; Lin, XJ<sup>3</sup>; Fu, Y<sup>4</sup>; Sun, QS<sup>5</sup>; Li, J<sup>6</sup>; Du, S<sup>7</sup>; Bai, S<sup>8</sup>.

**Review question / Objective:** Is Isoniazid Preventive Therapy effective and safe for preventing Tuberculosis in HIV-Infected Pregnant and Postpartum Women in high prevalence of tuberculosis counties.

**Condition being studied:** Human immunodeficiency virus (HIV).

**Information sources:** Pubmed, Embase, and Cochrane library will be searched to include randomized control trials which compared Isoniazid Preventive Therapy with placebo for preventing tuberculosis in HIV-Infected Pregnant and Postpartum Women. additional source including WHO clinical trial registry website, clinicaltrial.gov, conference abstracts, will also be searched. Further, the references of included trials will also be checked for more potential studies.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 July 2020 and was last updated on 03 July 2020 (registration number INPLASY202070011).

Pregnant and Postpartum Women in high prevalence of tuberculosis counties.

**Rationale:** Tuberculosis is the leading cause of health complications and death among persons with human

immunodeficiency virus (HIV) infection who reside in low-income and middle-income countries with a high tuberculosis burden. Among women, tuberculosis predominantly affects those of reproductive age. When tuberculosis develops during pregnancy or the early postpartum period, it is associated with adverse maternal, pregnancy, and infant outcomes.

**Condition being studied:** human immunodeficiency virus (HIV).

## METHODS

**Search strategy:** Pubmed, Embase, and Cochrane library will be searched to include randomized control trials which compared Isoniazid Preventive Therapy with placebo for preventing tuberculosis in HIV-Infected Pregnant and Postpartum Women, the search strategy will use keywords and mesh terms including "Isoniazid", "human immunodeficiency virus", "HIV", and "pregnant women", etc.

**Participant or population:** Pregnant women, at 14 weeks through 34 weeks of gestation, who had HIV infection and were 18 years of age or older.

**Intervention:** Isoniazid Preventive Therapy.

**Comparator:** Placebo.

**Study designs to be included:** Randomized control trials.

**Eligibility criteria:** This review will include trials assessing Isoniazid Preventive Therapy versus placebo for preventing Tuberculosis in HIV-Infected Pregnant and Postpartum Women in high prevalence of tuberculosis counties.

**Information sources:** Pubmed, Embase, and Cochrane library will be searched to include randomized control trials which compared Isoniazid Preventive Therapy with placebo for preventing tuberculosis in HIV-Infected Pregnant and Postpartum Women. additional source including WHO clinical trial registry website, [clinicaltrials.gov](http://clinicaltrials.gov), conference abstracts, will

also be searched. Further, the references of included trials will also be checked for more potential studies.

**Main outcome(s):** Incidence of TB, adverse events including but not limited to hepatotoxicity and peripheral neuropathy.

**Quality assessment / Risk of bias analysis:** Two investigators will independently assess the risk of bias (ROB) in individual studies by using the Cochrane Collaboration's Tool in the following aspects: The assessment includes sequence generation; allocation concealment; blinding of participants, personnel, and outcome assessors; incomplete outcome data; selective outcome reporting; and other sources of bias. Any differences between the authors on the data extraction and quality assessment will be resolved by discussion.

**Strategy of data synthesis:** RevMan version 5.3 will be used to perform all calculations related to the meta-analysis. Dichotomous data will be calculated in terms of a fixed or random effect model and expressed by the relative risk (RR) with 95% confidence interval (CI). Continuous data will be presented as mean difference and 95%CI. The inconsistency index (I<sup>2</sup>) and the  $\chi^2$ -based Cochran Q statistic will be applied for heterogeneity detection between clinical trials. When assessing the difference in outcome, heterogeneity involving all trials will be examined. A value of  $p < 0.05$  will be considered statistically significant.

**Subgroup analysis:** When there is obvious heterogeneity among included studies, we will perform a subgroup analysis in accordance with different study qualities if possible.

**Sensibility analysis:** In the case of sufficient trials data, the ROB tool will be used to assess methodological quality. If low-quality articles are deleted, a second meta-analysis will be performed. The results and effect size of the 2 meta-analyses will be compared and discussed.

**Country(ies) involved:** China.

---

**Keywords:** Isoniazid Preventive Therapy, HIV, Pregnant and Postpartum Women, Systematic review.

**Contributions of each author:**

Author 1 - Xiaozhuan Wang.

Author 2 - Yun Zhang.

Author 3 - Xiaojuan Lin.

Author 4 - Yu Fu.

Author 5 - Qingmei Sun.

Author 6 - Jing Li.

Author 7 - Song Du.

Author 8 - Jing Bai.