INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Incidence of active tuberculosis after the use of immune checkpoint inhibitors in cancer patients

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Review question / Objective: **To analyze the incidence of active tuberculosis after the use of immune checkpoint inhibitors in patients with cancer, and summarize the clinical characteristics of these patients.**
Condition being studied: **Active tuberculosis and cancers.**
Eligibility criteria: **(I) patients: malignancies which are histologically confirmed in tissue; (II) intervention: use of immune checkpoint inhibitors as anti-cancer treatment; (III) comparator: the potential effect of immunotherapy on tuberculosis activation; (IV) outcomes: incidence of active tuberculosis after using immune checkpoint inhibitors; (V) study design: randomized controlled trials, non-randomized controlled trials, epidemiological studies, and cohort studies.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 July 2022 and was last updated on 16 July 2022 (registration number INPLASY202270078).

INTRODUCTION

Review question / Objective: **To analyze the incidence of active tuberculosis after the use of immune checkpoint inhibitors in patients with cancer, and summarize the clinical characteristics of these patients.**

Condition being studied: **Active tuberculosis and cancers.**

METHODS

Participant or population: **Patients who are diagnosed with malignancies and treated with immune checkpoint inhibitors.**

Intervention: **Immunotherapy with immune checkpoint inhibitors.**

Comparator: Patients who are diagnosed with malignancies but have not received immune checkpoint inhibitors.

Study designs to be included: RCT and observational cohort studies.

Eligibility criteria: (I) patients: malignancies which are histologically confirmed in tissue; (II) intervention: use of immune checkpoint inhibitors as anti-cancer treatment; (III) comparator: the potential effect of immunotherapy on tuberculosis activation; (IV) outcomes: incidence of active tuberculosis after using immune checkpoint inhibitors; (V) study design: randomized controlled trials, non-randomized controlled trials, epidemiological studies, and cohort studies.

Information sources: PubMed, Embase, Web of Science, and Cochrane.

Main outcome(s): Incidence of active tuberculosis, which is defined as the proportion of patients who develop active tuberculosis among all patients receiving immune checkpoint inhibitors.

Quality assessment / Risk of bias analysis: The Newcastle-Ottawa Scale.

Strategy of data synthesis: We will perform analysis with non-comparative binary data in STATA software using random effects models.

Subgroup analysis: Male vs. female; lung cancer vs. non-lung cancers; different kinds of immune checkpoint inhibitors.

Sensitivity analysis: A sensitivity analysis was performed by removing one study at a time to evaluate whether the results could be significantly affected by a single study.

Language: English.

Country(ies) involved: China.

Keywords: Cancer; malignancies; immunotherapy; immune checkpoint inhibitors; tuberculosis.

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