INPLASY PROTOCOL

To cite: Yao et al. Dermatologic adverse events from immune-checkpoint inhibitors combination therapy: a systematic review and meta analysis. Inplasy protocol 202050068. doi: 10.37766/inplasy2020.5.0068

Received: 16 May 2020

Published: 16 May 2020

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Support: **Beijing Chao-Yang Hospital**

Review Stage at time of this submission: **Data extraction.**

Conflicts of interest:
None.

Dermatologic adverse events from immune-checkpoint inhibitors combination therapy: a systematic review and meta analysis

Yao, J[1]; Zhang, H[2]; An, G[3].

Review question / Objective: **The main research question of this article is whether immunotherapy combined with chemotherapy or targeted therapy increases the occurrence and severity of dermatologic side effects.**
Condition being studied: **Immune-checkpoint inhibitors:PD-1/PD-L1/CTLA-4 are promising cancer immunotherapy. Dermatologic safety profiles of their combination therapy are still poorly understood. This review aims to evaluate the incidence of selected dermatologic adverse effects (AEs) and provide more information for clinics.**
Information sources: **PubMed, Embase, Cochrane Library and the abstract from conference proceedings.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 16 May 2020 and was last updated on 16 May 2020 (registration number INPLASY202050068).

INTRODUCTION

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adverse effects (AEs) and provide more information for clinics.

METHODS

Search strategy: Three databases (PubMed, the Cochrane Library, and Embase) were systematically searched for randomized clinical trials (RCTs).

Participant or population: Patients under the age of 18 or with hematological malignancies(leukemia, lymphoma, multiple myeloma) and none-melanoma skin cancers were excluded.

Intervention: Immune-checkpoint inhibitors.

Comparator: Standard of care chemotherapy or placebo or targeted therapy.

Study designs to be included: Phase II/III RCT trails.

Eligibility criteria: First author, year of publication, study design, phase, type of therapy, line of therapy, underlying malignant neoplasm, analysis type, duration of therapy, dose of drug, age, sex, smoking, stage, BMI.ECOG-PS, region, numbers of patients who have dermatologic adverse events (rash, pruritus, alopecia) will be extracted.

Information sources: PubMed, Embase, Cochrane Library and the abstract from conference proceedings.

Main outcome(s): The incidence of dermatologic adverse events from immune-checkpoint inhibitors combination with chemotherapy or targeted therapy.

Additional outcome(s): The incidence of dermatologic adverse events from PD-1/ PD-L1 combination therapy.

Quality assessment / Risk of bias analysis: Risk of bias assessment will be carried out using the Cochrane Risk of Bias tool and completed by the two authors independently.

Strategy of data synthesis: The proportion of patients who developed treatment related cardiotoxicity from ICI or chemotherapy will be operationalized as an unadjusted odds ratio(OR) and 95% confidence interval(CI).

Subgroup analysis: The incidence of dermatologic adverse events from PD-1/ PD-L1 combination therapy.

Sensibility analysis: Immune checkpoint inhibitors; dermatological toxicities; adverse events; network meta-analysis.

Country(ies) involved: China.

Keywords: Immune immune-checkpoint inhibitors; dermatological toxicities; adverse events; meta-analysis.

Contributions of each author:
Author 1 - Jiannan Yao - Author 1 drafted the manuscript.
Author 2 - Huiyun Zhang - The author provided statistical expertise.
Author 3 - Guangyu An.