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The safety of PD-1 inhibitors combined with ADC drugs for tumor patients

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ADMINISTRATIVE INFORMATION

Support - National Natural Science Foundation of China.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202450022

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 May 2024 and was last updated on 06 May 2024.

INTRODUCTION

Review question / Objective This study aims to investigate the safety of PD-1 inhibitors combined with antibody-drug conjugates (ADCs) in tumor patients.

Condition being studied PD-1 inhibitors have achieved significant efficacy in the treatment of most tumors, prolonging the survival of patients. However, the overall effective rate is less than 30%. To increase their clinical efficacy, various combination treatment schemes have been attempted, including the combination of PD-1 inhibitors with antibody-drug conjugates (ADCs). This combination has achieved certain efficacy in tumors such as urothelial cancer and ovarian cancer. However, this brings about safety issues associated with treatment. PD-1 inhibitors and ADC drugs have different types of adverse reactions, and theoretically, this combined treatment may increase the adverse reactions in patients. However, there are currently no relevant studies that have summarized and compared this, we want to explore the safety of PD-1 inhibitors combined with ADC drugs for tumor patients through this meta-analysis.

METHODS

Participant or population The patients in the experimental group received treatment with a PD-1 inhibitor combined with ADC drugs. The patients in the control group received treatment with either a PD-1 inhibitor or an ADC drug alone.

Intervention PD-1 inhibitor combined with ADC drugs.

Comparator PD-1 inhibitor or an ADC drug alone.

Study designs to be included Randomized controlled trial or cohort study.

Eligibility criteria Inclusion: (1) Patients with malignant tumors, (2) randomized controlled study,

(3) the patients in the experimental group received treatment with a PD-1 inhibitor combined with ADC drugs, (4) the patients in the control group received treatment with either a PD-1 inhibitor or an ADC drug alone.
Exclusion (1) studies with unavailable original data, (2) non-English language literature, (3) ongoing studies, and (4) studies without full text.

Information sources The databases searched include PubMed, Embase, and Cochrane.

Main outcome(s) The incidence of various adverse reactions in different treatment groups. The assessment of adverse reactions is conducted using the Common Terminology Criteria for Adverse Events version 5.0 (CTCAE 5.0).

Quality assessment / Risk of bias analysis The risk of bias for each included study was assessed independently by two researchers using the Cochrane Handbook. The main sources of bias assessed included random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other biases.

Strategy of data synthesis Statistical analysis and forest plot were performed using Stata SE 16 software (Stata Corp, College Station, TX, USA). The pooled analysis results for the incidence of AEs were presented as OR with 95% CIs. Interaction tests were conducted to assess the differences in efficacy among these subgroups. The I2 test was used to evaluate heterogeneity among studies, with P 50% indicating significant heterogeneity, and a random-effects model was used. Conversely, $P > 0.1$ or $I2 < 50\%$ indicated no significant heterogeneity, and a fixed-effects model was used. All tests were two-sided, and $P < 0.05$ was considered statistically significant.

Subgroup analysis We will analyze the differences in various adverse reactions between patients of different genders, ages, stages, and number of treatment lines.

Sensitivity analysis Sensitivity analysis employs a method of sequential exclusion. The calculation is for the combined effect of the remaining documents after excluding one study. By observing the changes in the merged results, one can assess whether the original meta-analysis outcomes are significantly affected by certain studies.

Country(ies) involved China.

Keywords Immune Checkpoint Inhibitors, Antibody-Drug Conjugate, Tumor, Drug-Related Side Effects and Adverse Reactions.

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