

INPLASY

INPLASY202470117

doi: 10.37766/inplasy2024.7.0117

Received: 29 July 2024

Published: 29 July 2024

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Efficacy and safety of PD-1 inhibitors combined with/without chemotherapy in patients with recurrent or metastatic nasopharyngeal carcinoma: A systematic review and meta-analysis of Randomized Controlled Trials

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ADMINISTRATIVE INFORMATION**Support** - Not applicable.**Review Stage at time of this submission** - Preliminary searches.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202470117**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 July 2024 and was last updated on 29 July 2024.**INTRODUCTION**

Review question / Objective Comparing the efficacy and safety of PD-1 inhibitors alone or combined with chemotherapy in patients with recurrent/metastatic nasopharyngeal carcinoma.

Condition being studied Nasopharyngeal carcinoma (NPC) is an epithelial cancer originating from the mucosal lining of the nasopharynx and is highly associated with Epstein-Barr virus (EBV) infection. It is less common than other cancers, and as of 2020, more than 75% of NPC cases occur in southern China and Southeast Asia. Radiotherapy is the main treatment for early-stage nasopharyngeal cancer. Radiotherapy alone can cure about 90% of patients. However, due to the insidiousness and invasiveness of nasopharyngeal cancer, more than 70% of nasopharyngeal cancer patients have already been diagnosed when they are first diagnosed. It is locally advanced or metastatic disease.

METHODS

Participant or population Patients with recurrent or metastatic nasopharyngeal carcinoma.

Intervention PD-1 inhibitors combined with/without chemotherapy.

Comparator Chemotherapy.

Study designs to be included Randomized Controlled Trials.

Eligibility criteria Animal experiments, cell studies, reviews, meta-analyses, replications, case reports, or letters will not be considered and exclude studies with less than 10 patients. Two researchers independently identified potentially eligible articles through inclusion and exclusion criteria. Any disagreements regarding study inclusion were resolved by these two researchers or a third researcher.

Information sources Five database were searched: PubMed, Web of Science, Scopus, Embase and Cochrane Library.

Main outcome(s) ①OS: overall survival; ②PFS: progression-free survival; ③ORR: overall response rate; ④DCR: Disease control rate; ⑤TRAEs: treatment-related AEs.

Quality assessment / Risk of bias analysis We used the Cochrane Risk of Bias Assessment Tool to assess the risk of bias of the included RCTs. Bias assessment addressed four areas: random sequence generation; allocation concealment; blinding; incomplete outcome data and selective reporting. Each domain can be rated as “unclear” or “low” or “high” risk of bias accordingly.

Strategy of data synthesis Meta-analysis was performed in the presence of at least three included studies with available data for assessed outcomes using Revman 5.4 and STATA /MP 16.0. When $I^2 > 50\%$, using random-effects model; When $I^2 < 50\%$, using fixed-effects model.

Subgroup analysis PD-1 plus Chemotherapy vs Chemotherapy: or PD-1 vs Chemotherapy.

Sensitivity analysis Assess whether any individual study has an adverse impact on the pooled results by excluding it one by one.

Country(ies) involved China.

Keywords nasopharyngeal carcinoma, PD-1 inhibitors, chemotherapy, meta-analysis.

Contributions of each author

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