

INPLASY PROTOCOL

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None declared.

Evaluation of neoadjuvant immunotherapy plus chemotherapy in surgically resectable gastric cancer: A systematic review and meta-analysis

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Review question / Objective: Patient: the patients with advanced gastric cancer; intervention: neoadjuvant immunotherapy and chemotherapy; comparison: neoadjuvant chemotherapy; outcome: major pathological response (MPR) and pathological complete response (pCR) and safety assessed by grade 3–4 treatment-related adverse events (TRAEs) and postoperative complications; study: cohort studies.

Condition being studied: Gastric cancer (GC) is the fifth most common cancer and third leading cause of cancer-related deaths. To date, great progress has been made in understanding the pathogenesis of GC, and surgery remains the backbone of curative treatment. Although D2 radical surgery is beneficial, the 5-year survival rate of patients with GC remains below 50%.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 21 February 2023 and was last updated on 21 February 2023 (registration number INPLASY202320093).

INTRODUCTION

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METHODS

Participant or population: The patient with locally advanced gastric cancer.

Intervention: Neoadjuvant immunotherapy and chemotherapy.

Comparator: Neoadjuvant chemotherapy.

Study designs to be included: A meta-analysis of the non-comparative binary results was performed based on the most of the involved studies, which were one-arm clinical trials. For evaluating neoadjuvant therapy effectiveness and safety, the aggregated odds ratio (OR) and 95% confidence interval (CI) were transformed into occurrence rates.

Eligibility criteria: (a) prospective phase I, phase II or phase III clinical trials for pathologically diagnosed stage I–III resectable GC; (b) neoadjuvant therapy with ICI and chemotherapy; (c) reporting pCR, MPR, R0, grade 3 and 4 TRAEs and incidence of surgical complications as clinical outcomes.

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

Main outcome(s): Major pathological response (MPR) and pathological complete response (pCR) and safety assessed by grade 3–4 treatment-related adverse events (TRAEs) and postoperative complications.

Quality assessment / Risk of bias analysis: Since studies on neoadjuvant immunotherapy were mostly non-randomized single-arm clinical trial without comparison groups. Methodological Index for Nonrandomized Studies was used to assess the risk of bias in eligible studies.

Strategy of data synthesis: Pathological complete response (pCR) and major pathologic response (MPR) were used to evaluate the efficacy of neoadjuvant immunotherapy. Safety of neoadjuvant immunotherapy assessed by the incidence of grade 3–4 TRAEs and surgical complications. When the results of the included studies do not accord with the normal distribution, it is necessary to perform Freeman-Tukey double-arcsine transformation for raw incidence rates¹. The calculation of the effect index (P) and its standard error SE (P) of non-comparative binary outcomes was performed according to the formula. The incidence of events between any two groups was compared by risk ratio (RR) and its 95% confidence interval (CI). RR and 95% CI > 1 indicates that the incidence of events is lower than the control group, while < 1 indicates that the incidence is higher than the control group.

Subgroup analysis: Not applicable.

Sensitivity analysis: Not applicable.

Country(ies) involved: China.

Keywords: resectable advanced gastric cancer; neoadjuvant immunotherapy; perioperative immunotherapy.

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