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

Li, TY[1]; Xu, H[2]; Shao, GY[3].

Review question / Objective: **Patient: the patients with advanced gastric cancer; intervention: neoadjuvant immunotherapy and chemotherapy; comparision: 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) resporting 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 immuno-chemotherapy 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 immuno-chemotherapy; perioperative immunotherapy.

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