INPLASY

Safety and efficacy of immune checkpoint inhibitors for patients with triple-negative breast cancer: A systematic review and meta-analysis

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Corresponding author:
Leyi Yang

czfyll_123@163.com

Author Affiliation:
Zhangzhou Municipal Hospital.

Yan, X; Zhang, X; Huang, M; Yang, L.

ADMINISTRATIVE INFORMATION

Support - No applicable.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202450094

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 20 May 2024 and was last updated on 20 May 2024.

INTRODUCTION

Review question / Objective Comprehensively assess the safety and efficacy of ICI treatment for TNBC.

Condition being studied Many ongoing trials are investigating the treatment of triple-negative breast cancer (TNBC) patients with immune checkpoint inhibitors, so understanding the safety and efficacy of immune checkpoint inhibitors (ICIs) is crucial.

METHODS

Search strategy ((Immune Checkpoint Inhibitors[MeSH Terms]) OR (Checkpoint Inhibitors, Immune[Title/Abstract])) OR (Immune Checkpoint Inhibitor[Title/Abstract])) OR (Checkpoint Inhibitor, Immune[Title/Abstract])) OR (Immune Checkpoint Blockers[Title/Abstract])) OR (Checkpoint Blockers, Immune[Title/Abstract])) OR (Immune Checkpoint Blockade[Title/Abstract])) OR (Checkpoint Blockade, Immune[Title/Abstract])) OR (Immune Checkpoint Inhibition[Title/Abstract])) OR (Checkpoint Inhibition, Immune[Title/Abstract])) OR (PD-L1 Inhibitors[Title/Abstract])) OR (PD L1 Inhibitors[Title/Abstract])) OR (PD-L1 Inhibitor[Title/Abstract])) OR (PD L1 Inhibitor[Title/Abstract])) OR (Programmed Death-Ligand 1 Inhibitors[Title/Abstract])) OR (Programmed Death Ligand 1 Inhibitors[Title/Abstract])) OR (PD-1-PD-L1 Blockade[Title/Abstract])) OR (Blockade, PD-1-PD-L1[Title/Abstract])) OR (PD 1 PD L1 Blockade[Title/Abstract])) OR (CTLA-4 Inhibitors[Title/Abstract])) OR (CTLA 4 Inhibitors[Title/Abstract])) OR (CTLA-4 Inhibitor[Title/Abstract])) OR (CTLA 4 Inhibitor[Title/Abstract])) OR (Cytotoxic T-Lymphocyte-Associated Protein 4 Inhibitors[Title/Abstract])) OR (Cytotoxic T Lymphocyte Associated Protein 4 Inhibitors[Title/Abstract])) OR (Cytotoxic T-Lymphocyte-Associated Protein 4 Inhibitor[Title/Abstract])) OR (Cytotoxic T Lymphocyte Associated Protein 4 Inhibitor[Title/Abstract])) OR (PD-1 Inhibitors[Title/Abstract])) OR (PD 1

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Inhibitors[Title/Abstract])) OR (PD-1 Inhibitor[Title/Abstract])) OR (Inhibitor, PD-1[Title/Abstract])) OR (PD 1 Inhibitor[Title/Abstract])) OR (Programmed Cell Death Protein 1 Inhibitor[Title/Abstract])) OR (Programmed Cell Death Protein 1 Inhibitors[Title/Abstract])) OR (nivolumab[Title/Abstract])) OR (pembrolizumab[Title/Abstract])) OR (atezolizumab[Title/Abstract])) OR (ipilimumab[Title/Abstract])) OR (camrelizumab[Title/Abstract])) OR (toripalimab[Title/Abstract])) OR (tislelizumab[Title/Abstract])) OR (sintilimab[Title/Abstract])) OR (durvalumab[Title/Abstract])) OR (envafolimab[Title/Abstract])) OR (cemiplimab[Title/Abstract]) OR (oleclumab[Title/Abstract]) AND "breast cancer".

Participant or population All patients were adults and diagnosed with TNBC.

Intervention ICI.

Comparator Placebo.

Study designs to be included RCTs.

Eligibility criteria The inclusion criteria for the literature were as follows: (1) Patients: all patients were adults and diagnosed with TNBC; (2) Intervention and control: patients received ICI or placebo treatment, with all other treatment regimens being consistent across all patients; (3) Outcomes: any grade and grade ≥ 3 treatment-related adverse events (trAEs), irAEs, serious trAEs, specific grade ≥ 3 trAEs, specific any grade irAEs, pathological complete response (pCR), overall survival (OS), and progression free survival (PFS); and (4) Study design: all included studies were designed as RCTs.

Information sources PubMed, EmBase, and Cochrane Library databases.

Main outcome(s) Any grade and grade ≥ 3 treatment-related adverse events (trAEs), irAEs, serious trAEs, specific grade ≥ 3 trAEs, specific any grade irAEs.

Additional outcome(s) Pathological complete response (pCR), overall survival (OS), and progression free survival (PFS).

Data management Information extraction from the included studies was conducted by 2 authors following a standardized process, resolving any discrepancies through discussion until consensus was reached.

Quality assessment / Risk of bias analysis The two authors independently assessed the quality of the included studies using the Cochrane risk of bias tool. In cases of discordant results, they discussed the full text until reaching a consensus.

Strategy of data synthesis The safety outcomes of ICI treatment for TNBC are categorical data, and the relative risk ratio (RR) and its 95% confidence interval (CI) are calculated before data merging. Then hazard ratio (HR) with 95%CI were calculated for survival data, then a random-effects model is used to calculate the pooled effect estimate, which can account for potential differences among the included trials.

Subgroup analysis Subgroup analyses conducted based on the phase, disease status, treatments, and intervention.

Sensitivity analysis Stability of the pooled results was evaluated through sensitivity analysis.

Language restriction No restriction.

Country(ies) involved China.

Keywords immune checkpoint inhibitors; triple-negative breast cancer; systematic review; meta-analysis.

Contributions of each author

Author 1 - Xin Yan.
Email: 344968182@qq.com
Author 2 - Xiaoling Zhang.
Email: 842533596@qq.com
Author 3 - Yuanmao Huang.
Email: 47375669@qq.com
Author 4 - Leyi Yang.
Email: czfyll_123@163.com

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