

# INPLASY

## Neoadjuvant Immunotherapy for non-metastatic rectal Cancer: A systematic review and meta-analysis

INPLASY202470110

doi: 10.37766/inplasy2024.7.0110

Received: 28 July 2024

Published: 28 July 2024

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### ADMINISTRATIVE INFORMATION

**Support** - No.

**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202470110

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 28 July 2024 and was last updated on 28 July 2024.

### INTRODUCTION

**Review question / Objective** P: patients with primary cancer of the non-metastatic rectal cancer. I: neoadjuvant immunotherapy combined with or without chemotherapy or chemoradiotherapy, C: neoadjuvant antineoplastic scheme without immunotherapy. O: prognostic effectiveness. S: single-arm study, cohort or prospective study, retrospective study and RCTs.

**Condition being studied** Non-metastatic rectal cancer.

### METHODS

**Participant or population** It include patients with non-metastatic rectum cancer.

**Intervention** Receiving neoadjuvant immunotherapy combined with or without chemotherapy or chemoradiotherapy.

**Comparator** Neoadjuvant antineoplastic schemes without immunotherapy.

**Study designs to be included** Single-arm study, cohort or prospective study, retrospective study and RCTs.

**Eligibility criteria** The inclusion criteria were 1) English language, 2) patients with primary cancer of the rectal cancer, 3) nonmetastatic disease, 4) neoadjuvant immunotherapy (programmed cell death protein 1 [PD-1] inhibitor or cytotoxic T-lymphocyte-associated protein 4 inhibitor), and 5) reporting on 10 or more cases, 6) single-arm study, cohort or prospective study, retrospective study and RCTs.

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**Information sources** The following databases, PubMed, Embase, and Web of Science, the Cochrane Library, WanFang Database, China National Knowledge Infrastructure (CNKI), were searched. The search terms used included “rectal cancer,” “neoadjuvant immunotherapy,” “PD-1,” “PD-L1,” and “neoadjuvant therapy.”

**Main outcome(s)** Pathological complete response (pCRs), major pathological response (MPR), objective response rate (ORR), R0-resection and anus preserving rate.

**Quality assessment / Risk of bias analysis** The revised version of MINORS was used for the quality assessment of observational or non-randomized studies, while NOS scores guideline was used for the quality assessment of controlled clinical or cohort studies. The third reviewer (JXX) resolved the inconsistencies between the above two authors.

**Strategy of data synthesis** STATA/SE version 15.1 was used for all statistical analyses. A random-effect model was employed, and heterogeneity between studies was categorized as low (I<sup>2</sup> 50%) using the Cochran Q chi-square test and I<sup>2</sup> statistics. Sensitivity analysis was conducted by sequentially excluding studies contributing to high heterogeneity in pooled data.

**Subgroup analysis** Secondary outcomes (pCRs and MPR) of subgroup analysis between deficient mismatch repair/microsatellite instability-high group (dMMR/MSI-H) and proficient mismatch repair/microsatellite stable group (pMMR/MSS), female and male groups, early stage group and locally advanced stage group were analyzed for the final results.

**Sensitivity analysis** In order to ensure the stability of the primary outcomes, we will perform sensibility analysis of these studies with high risk of bias according to sample size, study design, heterogeneity qualities etc.. If the result of sensitivity analysis is quite different from meta-analysis, we will consider to conduct descriptive analysis.

**Country(ies) involved** China.

**Keywords** non-metastatic rectal cancer; neoadjuvant immunotherapy; meta-analysis.

#### **Contributions of each author**

Author 1 - Huan Zhang - Data curation, Formal analysis, Methodology, Investigation, Project

administration, Software, Supervision, Validation, Visualization, Writing – review & editing.

Author 2 - Laiyan Zhou - Data curation, Formal analysis, Project administration, Resources, Supervision, Visualization, Writing – review & editing.

Author 3 - Jianxin Xue - Conceptualization, Formal analysis, Investigation, Methodology, Project administration, Visualization, Writing – review & editing.