INPLASY PROTOCOL

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Corresponding author:
Yong Xin

deep369@163.com

Author Affiliation:
Affiliated Hospital of Xuzhou Medical University.

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None declared.

Evaluation of clinical and safety outcomes of neoadjuvant immunotherapy combined with chemoradiotherapy for patients with locally advanced rectal cancer：A meta-analysis of single-arm trials

Xin, Y[1]; Zhu, YQ[2]; Cui, JJ[3]; Chen, JZ[4]; Lou, YF[5].

Review question / Objective: **To evaluate the clinical efficacy and safety of neoadjuvant immunotherapy combined with chemoradiotherapy for locally advanced rectal cancer.**
Condition being studied: **Rectal cancer is the third most common cause of cancer death worldwide, with over 1.85 million cases and 850000 deaths annually.Although the multidisciplinary treatment (MDT) method of neoadjuvant chemotherapy combined with surgery effectively controls local recurrence, the distant recurrence and metastasis rate is still high. With the development of immunotherapy in recent years, the treatment plans for rectal cancer have changed and greatly improved the survival prognosis of patients. The purpose of this meta-analysis is to use existing data for analysis to evaluate the safety and effectiveness of neoadjuvant immunotherapy combined with chemoradiotherapy for rectal cancer patients, laying the foundation for subsequent research.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 26 April 2023 and was last updated on 26 April 2023 (registration number INPLASY202340094).

INTRODUCTION

Review question / Objective: **To evaluate the clinical efficacy and safety of neoadjuvant immunotherapy combined with chemoradiotherapy for locally advanced rectal cancer.**

Condition being studied: **Rectal cancer is the third most common cause of cancer death worldwide, with over 1.85 million cases and 850000 deaths annually.Although the multidisciplinary treatment (MDT) method of neoadjuvant chemotherapy combined with surgery effectively controls local recurrence, the distant recurrence and metastasis rate is still high. With the**

development of immunotherapy in recent years, the treatment plans for rectal cancer have changed and greatly improved the survival prognosis of patients. The purpose of this meta-analysis is to use existing data for analysis to evaluate the safety and effectiveness of neoadjuvant immunotherapy combined with chemoradiotherapy for rectal cancer patients, laying the foundation for subsequent research.

METHODS

Participant or population: Patient were confirmed to have rectal cancer by routine examination and met the diagnostic criteria for locally advanced rectal cancer.

Intervention: Neoadjuvant immunotherapy combined with chemoradiotherapy.

Comparator: None.

Study designs to be included: Single-arm trials.

Eligibility criteria: We included single-arm studies in which the intervention was neoadjuvant immunotherapy plus chemoradiotherapy; all the patients had pathologically confirmed locally advanced rectal cancer.

Information sources: PubMed, Embase, Conchrane library, Web of Science, Chinese National Knowledge Infrastructure (CNKI), Chinese Biological Medicine(CBM) Database, Wanfang Database and the VIP Database, the International Clinical Trial Registry Platform (ICTRP) and the Chinese Clinical Registry.

Main outcome(s): CR, PR, SD, PD, pCR rate, ORR, R0 resection rate, CCR, MPR, DCR, the incidence of postoperative complications, adverse reactions.

Quality assessment / Risk of bias analysis: Methodological Index for Nonrandomized Studieshe cochrane collaboration's tool and the Newcastle-Ottawa scale.

Strategy of data synthesis: All statistical analyses will be performed using Stata software(version 15).

Subgroup analysis: None.

Sensitivity analysis: The sensitivity analyses will be performed by excluding one study at a time to assess the influence of each study on overall results.

Country(ies) involved: China.

Keywords: Rectal Neoplasms, Neoadjuvant chemoradiotherapy, programmed cell death 1 (PD-1), programmed cell death ligand 1 (PD-L1), immunotherapy, Systematic review.

Contributions of each author:
Author 1 - Yong Xin.
Email: deep369@163.com
Author 2 - Youqi Zhu.
Email: 1765691151@qq.com
Author 3 - Junjie Cui.
Email: 784154883@qq.com
Author 4 - Jiuzhou Chen.
Email: 476701362@qq.com
Author 5 - Yufei Lou.
Email: 583936230@qq.com