INPLASY

Treatment of Postoperative Recurrence of Crohn's Disease: A Systematic Review and Network Meta-analysis Protocol

INPLASY2023110021
doi: 10.37766/inplasy2023.11.0021
Received: 05 November 2023
Published: 05 November 2023

Jiang, TX[1]; Liu, CJ[2]; Zhang, B[3].

Corresponding author:
Bo Zhang

zhangbo_scu@scu.edu.cn

Author Affiliation:
Gastric Cancer Center, West China Hospital, Sichuan University, Chengdu, China.

ADMINISTRATIVE INFORMATION

Support - NA.

Review Stage at time of this submission - The review has not yet started.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY2023110021

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 05 November 2023 and was last updated on 05 November 2023.

INTRODUCTION

Review question / Objective To elucidate the comparative efficacy and safety profiles of various treatment for postoperative recurrence Crohn's disease.

Condition being studied Crohn's disease (CD) is a chronic inflammatory disorder affecting the gastrointestinal tract, and for patients presenting with intricate conditions such as intestinal stenosis and/or perforation, surgery emerges as the preferred therapeutic choice. However, surgery can not cure the disease completely and the risk of recurrence still exists.The predominant approach to managing postoperative recurrence CD involves steroid therapies, monoclonal antibody treatments, immunomodulators, and reoperation. Regrettably, the existing evidence remains insufficient to ascertain which of these treatments is more efficacious or safer. Thus, we are planning a comprehensive network meta-analysis and systematic review to elucidate the comparative efficacy and safety profiles of various treatment for postoperative recurrence CD.

METHODS

Participant or population 1. Pathologically confirmed CD; 2. Underwent ileocolonic resection for CD; 3. Postoperative endoscopic or clinical recurrence.

Intervention This study will include studies comparing at least two different interventions from the following: corticosteroids, sulfasalazine, mesalazine, azathioprine, methotrexate, vedolizumab, infliximab, adalimumab, certolizumab pegol, ustekinumab, risankizumab, and reoperation.

Comparator This is a network meta-analysis and all interventions are described in the Intervention section.

Study designs to be included The study will include both non-randomized studies (NRSs) and randomized controlled trials (RCTs), the former including prospective or retrospective cohort studies. The RCT and NRS studies will be synthesized and analyzed separately. Full-text publications, results published in non-commercial trial registries and abstracts with sufficient information on study design, participant characteristics, interventions and outcomes will be included.

Eligibility criteria There are not any other inclusion or exclusion criteria not defined in the PICOS section.

Information sources PubMed, EMBASE, the Cochrane Central Register of Controlled Trials and Web of Science (from inception to January 2024) will be searched for published studies, without language restriction.

Main outcome(s) The primary outcomes are as follows:
1. Endoscopic response and endoscopic remission (based on Rutgeerts' score).
2. For endoscopic recurrence: Clinical recurrence rate at 6 months, 1 year, 2 years or longer.
3. For clinical recurrence: Clinical remission (based on Harvey-Bradshaw Index or Crohn's Disease Activity Index (CDAI)) and serological remission (CRP, ESR, FC, and so on).
The secondary outcomes are as follows:
1. Treatment failure for various reasons, such as adverse events, disease recurrence, or other reasons.
2. Incidence of adverse events.

Quality assessment / Risk of bias analysis . For NRSs - The tool of risk of bias in non-randomised studies of interventions (ROBINS-I) will be used to estimate the risk of bias of the included prospective or retrospective cohort studies. Seven domains of bias throughout the entire course of intervention were well evaluated in this tool: (1) bias due to confounding, (2) bias in selection of participants into the study, (3) bias in classification of interventions, (4) bias due to deviations from intended intervention, (5) bias due to missing data, (6) bias in measurement of outcomes and (7) bias in selection of the reported result. Overall bias after seven domains will be estimated. On the condition of comprehensive consideration above, each individual included study will be assessed as having the low, moderate, serious and critical risk of bias. If critical information is lacking for the evaluation of the risk of bias, such studies will be estimated as having no information

2. For RCTs
The risk-of-bias tool from Cochrane Handbook V.6.4 will also be used if random controlled trials are included. Six domains of risk of bias will be evaluated as follows: random sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias. Each eligible study with abundant information will be judged as having a low or high risk of bias. Otherwise, it will be evaluated as unclear.

Strategy of data synthesis When quantitative analyses were not possible, we described the results narratively. If quantitative analyses are feasible, subsequent statistical analyses will be performed. The RCT and NRS will be synthesized and analyzed separately.

Subgroup analysis When significant heterogeneity is found, subgroup analyses will be used to identify and interpret the source. Meta-regression can be used as a further supplementary method if data are available. Preliminary groupings are shown below:
- Recurrence status (endoscopic or clinical).
- Postoperative prophylactic medication (yes or no).

Sensitivity analysis If possible, sensitivity analyses will be performed to check for stability by excluding studies with a high risk of bias.

Country(ies) involved China.

Keywords Treatment, Postoperative Recurrence, Crohn's Disease, Network Meta-analysis.

Contributions of each author
Author 1 - Tianxiang Jiang.
Author 2 - Chunjuan Liu.
Author 3 - Bo Zhang.