INPLASY

The Impact of Saccharomyces boulardii on Gut Microbiota Modulation in Inflammatory Bowel Disease: A Systematic Review and Meta-Analysis

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Preliminary searches.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202580030

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 9 August 2025 and was last updated on 9 August 2025.

INTRODUCTION

Review question / Objective The aim of this randomized controlled trial meta-analysis was to find out the differences in efficacy and safety between them based on the results The effect of using Saccharomyces boulardii on the regulation of gut microbiota in patients with inflammatory bowel disease. To assess the efficacy and safety of Saccharomyces boulardii for induction of remission in patient with Inflammatory bowel disease Population:Inflammatory bowel disease Intervention:Saccharomyces boulardii Comparsion:Placebo Outcome:Efficiency in gut Microbiota ModulationStudy:RCT.

Condition being studied Inflammatory bowel disease (IBD), including Crohn's disease and ulcerative colitis, is characterized by chronic relapsing intestinal inflammation. It has been a worldwide health-care problem with a continually increasing incidence. It is thought that IBD results from an aberrant and continuing immune response to the microbes in the gut, catalyzed by the genetic susceptibility of the individual. Although the etiology of IBD remains largely unknown, it involves a complex interaction between the genetic, environmental or microbial factors and the immune responses.
Despite this, some important questions about Saccharomyces boulardii in Inflammatory Bowel Disease remain unanswered. These include determining the optimal dosing regimen for both safety and durability, identifying the ideal timing oral saccharomyces boulardii treatment before irreversible bowel damage occurs, and deciding whether to use a top-down or step-up approach tailored to the individual patient's disease location, behavior, and other predictors.

METHODS

Participant or population Randomized controlled trials that enrolled patients should fulfill the Inflammatory bowel disease diagnostic criteria.
All patients with Inflammatory bowel disease will be included without limitation of age, race, sex, economic level, and severity.

Intervention All types of oral Saccharomyces boulardii drugs, including tablets, capsules, solutions, etc.

Comparator Placebo.

Study designs to be included This systematic review included only those RCTs that had been peer-reviewed. All RCTs comparing topic with oral Saccharomyces boulardii in the relevant database were included in this paper. Non randomized controlled trials, review reports ,pathological reports and only summary or meeting reports were excludedThis systematic review included only those RCTs that had been peer-reviewed. All RCTs comparing topic with oral Saccharomyces boulardii in the relevant database were included in this paper. Non randomized controlledtrials,review reports ,pathological reports and only summary or meeting rep.

Eligibility criteria We will make a standard data collection sheet before data extraction. Two reviewers will independently extract data from the selected studies and fill in the data collection sheet. Discrepancies and uncertainties will be resolved by consensus between the 2 review authors by asking the third author to make a final decision. We will extract the following data: 1. General information: the first author, title, the journal, publication type, publication year, country; 2. Methods: study design, sample size, randomization, allocation concealment, blinding methods, inclusion criteria, and exclusion criteria; 3.Participants: All patients with Inflammatory bowel disease will be included without limitation of age, race, sex, economic level, and severity;4. Interventions:All types of oral Saccharomyces boulardii drugs, including tablets, capsules, solutions, etc; 5. Outcomes: primary and secondary outcomes, adverse effects, and follow up.

Information sources We will search articles in four electronic databases including PubMed, Embase, Cochrane Library and Web of Science. All the English publications until August 2025 will be searched without any restriction of countries or article type.
Reference list of all selected articles will independently be screened to identify additional studies left out in the initial search.

Main outcome(s) The main outcome measures of this review were the safety and efficacy of the effect of oral Saccharomyces boulardii on gut microbiota regulation in patients with inflammatory bowel disease compared with oral placebo.

Quality assessment / Risk of bias analysis Two review authors will independently use the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions to assess the risk of bias in the included studies.

Strategy of data synthesis We will use RevMan 5.3 for all statistical analysis. If considerable heterogeneity is observed, joint effect estimates are analyzed using a 95% CI stochastic effects model. If necessary, each subgroup will be analyzed carefully.

Subgroup analysis There is no pregrouping plan. Subgroup analysis was performed based on control interventions and different outcomes. As there are few literatures to be included and there is no great difference, subgroup analysis is not carried out.

Sensitivity analysis We will use RevMan for all statistical analysis. If considerable heterogeneity is observed, joint effect estimates are analyzed using a 95% CI stochastic effects model. If necessary, each subgroup will be analyzed carefully.

Country(ies) involved China.

Keywords Inflammatory Bowel Disease; Saccharomyces boulardii; Gut Microbiota Modulation.

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