

INPLASY PROTOCOL

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Mesenchymal stem cell versus vedolizumab in the treatment of complex perianal fistula of crohn disease: a systematical review and indirect comparison

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Review question / Objective: P: Patients with complex fistulizing crohn disease. I: mesenchymal stem cell or vedolizumab. C: Placebo. O: The primary outcome was the proportion of patients with fistula response. Secondary outcomes included the proportion of patients who achieved fistula remission. S: RCT.

Information sources: We searched electronic database through PubMed, Embase, Web of Science, Cochrane library and Clinicaltrial.gov for literature since initiation until April 7, 2020 without any language restrictions.

Main outcome(s): A 50% closure or more from baseline in the number of active fistulas.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 April 2020 and was last updated on 07 April 2020 (registration number INPLASY202040037).

INTRODUCTION

Review question / Objective: P: Patients with complex fistulizing crohn disease. I: mesenchymal stem cell or vedolizumab. C: Placebo. O: The primary outcome was the

proportion of patients with fistula response. Secondary outcomes included the proportion of patients who achieved fistula remission. S: RCT.

Condition being studied: Crohn disease is a chronic inflammatory disease of the gastrointestinal tract, with features of relapses and remissions. The disease is prolonged and difficult to cure, leading to intestinal damage and various complications. Fistula is a relatively common complication of Crohn's disease, reported in 17%–50% of patients from population-based cohort studies. Tumor necrosis factor inhibitors therapy has been proved to have significant efficacy in the treatment of fistulizing Crohn's disease. But TNF inhibitors has a limited effect on some patients with refractory fistulas. At the same time, novel therapies and biologics, such as anti-integrins(vedolizumab) and mesenchymal stem cell, have also emerged and demonstrated a good trend for treatment of complex fistulas. We aim to conduct a systematic review and indirect comparison to assess the efficacy and safty (when available) of vedolizumab therapy for complex fistulizing crohn disease.

METHODS

Participant or population: Patients with crohn disease with complex perianal fistulas.

Intervention: mesenchymal stem cell or vedolizumab.

Comparator: Placebo.

Study designs to be included: RCT.

Eligibility criteria: Eligible studies were 1. randomized-controlled trials that enrolled adult CD patients (18 years of age or older) with complex perianal fistulizing disease. 2. Interventions of interest included mesenchymal stem cell or vedolizumab. 3. studies in the English language only. 4. studies in full-text format, and 5.retrospective studies, Case reports, review articles, conference abstract and letters were excluded from the analysis.

Information sources: We searched electronic database through PubMed,

Embase, Web of Science, Cochrane library and Clinicaltrial.gov for literature since initiation until April 7, 2020 without any language restrictions.

Main outcome(s): A 50% closure or more from baseline in the number of active fistulas.

Additional outcome(s): Complete fistula closure, resolution on imaging and long-term fistula closure rate, perianal disease activity (PDAI) or fistula drainage assessment index (FDAI). Adverse events(AEs), serious adverse events(SAEs) and opportunistic infections will also be recorded when available.

Quality assessment / Risk of bias analysis: The risk of bias of included studies will be assessed by two authors independently using the the Cochrane risk of bias tool. Seven domains of the Cochrane risk of bias tool contains: sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other potential sources of bias.

Strategy of data synthesis: Analysis will be performed using Review Manager 5.3 (RevMan 5.3) and ITC(indirect treatment comparision) software, and the results will be expressed as odds ratios (OR) with 95% confidence intervals (CIs) .Statistical heterogeneity will be assessed by the χ^2 test and I^2 statistic. The I^2 statistic reflects the percentage of variation between studies because of heterogeneity rather than chance only with values ranging from 0% (no heterogeneity) to 100% (maximal heterogeneity). For the analysis of heterogeneity ($I^2 > 50\%$ or $P > 50\%$ or a P value < 0.1 for the χ^2 were considered a marker of significant heterogeneity. Sensitivity analysis will be used for conducting this meta-analysis. Bucher's method will be done for indirect comparision.

Subgroup analysis: None.

Sensibility analysis: We will conduct a sensitivity analysis based on risk of bias and quality of the research.

Countries involved: China.

Keywords: crohn disease; fistula; mesenchymal stem cell; vedolizumab; indirect comparison.

Contributions of each author:

Author 1 - The author will select eligible studies, extract information, perform data analysis and draft the manuscript.

Author 2 - The author will select eligible studies, extract information.

Author 3 - The author will resolve discrepancies encountered during study selection and data extraction.