INPLASY PROTOCOL

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Support: **None**

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

Conflicts of interest:
None.

Efficacy and safety of infliximab versus adalimumab in the therapy of fistulizing Crohn disease: a systematic review and indirect comparison

Wu, GZ[1]; Zhai, Zipeng[2]; Zhu, Yu[3]; Guo, Qinghong[4].

Review question / Objective: **We aim to compare efficacy and safety of infliximab with adalimumab in fistulizing Crohn disease.**
Condition being studied: **Crohn disease is a chronic inflammatory disease of the gastrointestinal tract, leading 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 (including infliximab and adalimumab)has been proved to have significant efficacy in the treatment of fistulizing Crohn disease. But it is unclear the difference of efficacy and safety between infliximab and adalimumab.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 15 April 2020 and was last updated on 15 April 2020 (registration number INPLASY202040089).

INTRODUCTION

Review question / Objective: **We aim to compare efficacy and safety of infliximab with adalimumab in fistulizing Crohn disease.**

Rationale: **The difference between the efficacy and safety of the two therapies.**

Condition being studied: **Crohn disease is a chronic inflammatory disease of the gastrointestinal tract, leading 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 (including infliximab and adalimumab)has been proved to have significant efficacy in the treatment of fistulizing Crohn disease. But it is unclear the difference of efficacy and safety between infliximab and adalimumab.

METHODS

Participant or population: Patients with fistulizing Crohn disease.

Intervention: Infliximab or adalimumab.

Comparator: Placebo.

Study designs to be included: Randomized controlled trials.

Eligibility criteria: Inclusion criteria: 1.Adult CD patients (18 years of age or older) with fistulas; 2. Interventions of interest included infliximab or adalimumab; 3.Studies evaluating fistula healing and safety profile of treatments; 4.Study design limited to RCTs. Exclusion criteria: 1. Studies only assessing efficacy or safety of therapies for active Crohn disease without providing any data about fistula healing; 2. Review, letter, conference, observational study.

Information sources: Electronic databases including PubMed, Embase, Web of Science, Cochrane library and clinicaltrials.gov were searched for articles from inception to April 9, 2020. Non-English articles were excluded from our search result.

Main outcome(s): 1.Induction of fistula response and remission(defined as a 50% reduction from baseline in the number of open actively draining fistulas and a 100% reduction, respectively). 2.Safety profile including adverse effects, sevious adverse effects, infectious adverse effects, infusion reactions.

Additional outcome(s): None.

Quality assessment / Risk of bias analysis: Two authors will separately evaluate the risk of bias using 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: Clinical heterogeneity will be evaluated by reviewing differences across trials in characteristics of trial design, duration of follow-up and randomized patients. Heterogeneity of included studies will be assessed based onχ^2 test and I^2 statistic. For the analysis of heterogeneity (I^2>50% or P50% or a P value<0.1 for the χ^2 will be considered a marker of significant heterogeneity. Bucher's method will be done for indirect comparision. Review Manager 5.3 (RevMan 5.3) and ITC (indirect treatment comparision) software will be used to perform a data analysis.

Subgroup analysis: None.

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

Country(ies) involved: China.

Keywords: Crohn disease, fistula, infliximab, adalimumab, indirect comparison.

Contributions of each author:
Author 1 - The author will select eligible studies, assess risk of bias and extract information, perform data analysis and draft the manuscript.
Author 2 - The author will select eligible studies, assess risk of bias and extract information.
Author 4 - The author will resolve discrepancies encountered during study selection and data extraction.