

INPLASY PROTOCOL

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None.

Banxia Xiexin Decoction in the treatment of Hp-associated peptic ulcer: A protocol for systematic review and meta-analysis

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Review question / Objective: The present meta-analysis aimed at evaluating the efficacy and safety of Banxia Xiexin decoction in the treatment HP positive peptic ulcer.

Condition being studied: Studies suggested Banxia Xiexin Decoction is effective in the treatment of HP positive peptic ulcer.

Information sources: PubMed, Web of Science, Cochrane Library, and Chinese biomedical databases will be searched from their inceptions to the October 31st, 2020.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 01 December 2020 and was last updated on 01 December 2020 (registration number INPLASY2020120002).

INTRODUCTION

Review question / Objective: The present meta-analysis aimed at evaluating the efficacy and safety of Banxia Xiexin decoction in the treatment HP positive peptic ulcer.

Condition being studied: Studies suggested Banxia Xiexin Decoction is effective in the treatment of HP positive peptic ulcer.

METHODS

Participant or population: The patients should be those who undergone Hp positive PU. We will not apply any restrictions of race, age, education background, and economic status.

Intervention: Banxia Xiexin Decoction combined with lansoprazole triple therapy.

Comparator: Lansoprazole triple therapy

Study designs to be included: Randomized controlled trials.

Eligibility criteria: 2.1.1. Type of study. This study will only include high quality randomized controlled trials. 2.1.2. Type of patients. The patients should be those who undergone Hp positive PU. We will not apply any restrictions of race, age, education background, and economic status. 2.1.3. Intervention and comparison. This study will compare Banxia Xiexin Decoction combined with lansoprazole triple therapy and alone lansoprazole triple therapy for treating Hp positive PU. 2.1.4. Type of outcomes. The primary outcome is Hp eradication rate. The secondary outcomes include traditional Chinese medicine syndrome score, quality of life score, gastrin level, incidence of adverse reactions and recurrence rate.

Information sources: PubMed, Web of Science, Cochrane Library, and Chinese biomedical databases will be searched from their inceptions to the October 31st, 2020.

Main outcome(s): The primary outcome is Hp eradication rate.

Additional outcome(s): The secondary outcomes include traditional Chinese medicine syndrome score, quality of life score, gastrin level, incidence of adverse reactions and recurrence rate.

Quality assessment / Risk of bias analysis: The Grading of Recommendations Assessment, Development, and Evaluation will be used to assess the quality of evidence. It contains 5 domains (bias risk, consistency, directness, precision, and publication bias). And the quality of evidence will be rated as high, moderate, low, and very low.

Strategy of data synthesis: The STATA version 15.1 software (Stata Corporation, College Station, TX, USA) will be used for meta-analysis. We calculated the pooled summary odds ratio (OR) and its 95% confidence interval (CI). The Cochran's Q-statistic and I² test will be used to evaluate

potential heterogeneity between studies.[9] If the Q-test shows a P50%, indicating significant heterogeneity, and the random effect model will be employed or if heterogeneity is not significant, the fixed-effects model was used.

Subgroup analysis: If it is possible, we will perform meta-analysis to analyze the pooled outcome data when acceptable homogeneity has been identified. Otherwise, we will conduct subgroup analysis to investigate potential causes for substantial heterogeneity among eligible studies.

Sensibility analysis: Sensitivity analysis will be performed to evaluate the influence of a single study on the overall estimate.

Country(ies) involved: China.

Keywords: Banxia Xiexin decoction, Helicobacter pylori, Meta-analysis, peptic ulcer.

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